JUDGE CROTTY

23 CV 09122

IN THE UNITED STATES DISTRICT COURT

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, THE DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA, STATE OF MARYLAND, STATE OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MISSOURI, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW HAMPSHIRE, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF OREGON, COMMONWEALTH OF PUERTO RICO, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, STATE OF VERMONT, STATE OF VIRGINIA, STATE OF WASHINGTON, STATE OF WISCONSIN, ex rel. ELIZABETH SAENGER, PhD, Plaintiff vs. MEDSCAPE, LLC, WEBMD HEALTH CORP., WEBMD, LLC, WEBMD GLOBAL LLC, MH SUB I, LLC, d/b/a INTERNET BRANDS, HEALTHCARE PERFORMANCE CONSULTING, CE OUTCOMES, LLC. Defendants	CASE NO. COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT 31 U.S.C. §§ 3729, et seq. FILED IN CAMERA AND UNDER SEAL pursuant 31 U.S.C. §3730(b)

FALSE CLAIMS ACT COMPLAINT "QUI TAM"

TO THE HONORABLE JUDGE CROTTY OF SAID COURT:

The United States of America and the above-named Plaintiff-States, by and through qui tam Relator-Plaintiff, Elizabeth Saenger, PhD, brings this action under 31 U.S.C. §§ 3729 *et seq.*, ('federal FCA') and of the above-named Plaintiff-States ('State FCAs') (collectively, the 'False Claims Act"') to rectify Defendants' violations of the federal and states' False Claims Acts and Medicaid fraud statutes and to recover from Medscape, LLC, et al. all damages, penalties, and other remedies available under the False Claims Act on behalf of the United States, the Plaintiff-States and herself.

This action is one to recover damages and civil penalties on behalf of the United States of America arising from the collusion and conspiracy between Medscape, LLC, WebMD, CE Outcomes, LLC, Healthcare Performance Consulting, and MH Sub I, LLC, dba Internet Brands, which purchased WebMD in 2017, (collectively, 'the Defendants') and various pharmaceutical companies to promote the companies' pharmaceutical agents. However, as discovered by the Relator when she was employed as an Editorial Director by Medscape, Medscape employs a strategy that the Relator describes as a 'Trojan Horse' methodology wherein off-label, misleading, and untruthful statements are embedded within continuing medical education (CME)[1] courses offered through Medscape, a member of the WebMD Health Professional Network, Inc.

These statements, as documented by the firsthand and original knowledge of Relator Elizabeth Saenger, PhD and described with specificity within the corpus of this Complaint were, and are, embedded within secret content in thousands, of CME 'education courses' offered through

[1] The abbreviation, CME will be used throughout this complaint to signify continuing medical education for physicians; continuing education (CE) applies to all licensed medical professionals, whereas CME applies primarily to physicians. Simply put, all CME is CE, but not all CE is CME. Continuing education units (CEU) is a measure used in continuing education programs to help a provider maintain their license.

Medscape, a member of the WebMD Health Professional Network, Inc. of the 1,200 programs published in 2015, some 90% having embedded content. The dates of the infractions range from 2004 to the present day, suggestive of a continuing conspiracy and fraud upon the U.S. and State governments, all to the detriment of the U.S. taxpayer.

As a result of this conspiracy, the prescriptions of the drugs discussed herein and others, especially, the opioids, skyrocketed with particularly detrimental economic effects on Medicare, Medicaid, the Veterans Administration, TRICARE, Federal Employees Health Benefits Program, and the Office of Workers' Compensation Programs of the U.S. Department of Labor, collectively, the 'Government Healthcare Programs' and adverse health effects on people to whom the drugs were prescribed.

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X. CAUSES OF ACTION

INTRODUCTION

1. The United States of America and the above-named Plaintiff-States, by and through qui tam Relator-Plaintiff, Elizabeth Saenger, PhD, bring this action under 31 U.S.C. §§ 3729 *et seq.*, ('federal FCA') and of the above-named Plaintiff-States ('State FCAs') (collectively, the 'False Claims Act"') to rectify Defendants' violations of the federal and states' False Claims Acts and Medicaid fraud statutes and to recover from Medscape, LLC, et al. for all damages, penalties, and other remedies available under the False Claims Act on behalf of the United States, the Plaintiff-States and herself.

2. This action is also brought under the respective qui tam provisions of False Claims Acts (or similarly named statutes) on behalf of the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Missouri, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Oregon, the Commonwealth of Puerto Rico, the State of Tennessee, the State of Texas, the State of Vermont, the Commonwealth of Virginia, the State of Washington, and the State of Wisconsin.

3. The gravamen of the Relator's claims is that the Defendants collectively, for at least the past twenty (20) years, have aided, abetted, colluded, and conspired with various pharmaceutical companies to develop and execute a sophisticated marketing plan through

Medscape's online continuing medical education programs (CME)[2], with the purpose of promoting the companies' pharmaceutical products off-label, untruthfully, in a misleading way, and/or in a false manner in order to induce physicians to increase the prescribing of the drugs. These activities, still in place today, demonstrate a continuing pattern of malfeasance including violation of the law, violation of the Accreditation Council for Continuing Medical Education (ACCME)[3] and violation of the Food and Drug Administration (FDA)'s Guidance on Industry-Supported Scientific and Educational Activities. (FDA's Guidance) [4]

4. Defendants knew when they initiated this marketing scheme that there was little, and in some cases no, credible scientific basis to justify the assertions made in many of their online CME presentations. As a result, prescriptions of these drugs (especially, those of the opioids), skyrocketed, with particularly detrimental economic effects on Medicare, Medicaid, the Veterans Administration, TRICARE, Federal Employees Health Benefits Program, and the Office of Workers' Compensation Programs of the U.S. Department of Labor, collectively, the 'Government Healthcare Programs'.

5. The Relator has complied with all procedural requirements of the laws under which this case is brought.

[2] Continuing medical education programs serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession.

[3] Accreditation Council for Continuing Medical Education https://acCME.org/ (Accessed May 10, 2023).

[4] FDA. Guidance for Industry: Industry-Support for Scientific and Educational Activities. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/industry-supported-scientific-and-educational-activites. (Accessed May 13, 2023).

II. PARTIES

6. The Relator, Plaintiff Elizabeth Saenger, PhD, grew up in the Bronx, NY, and has maintained her primary residence in Manhattan, NY since May of 1997. She is a citizen of the State of New York.

7. Defendant Medscape's corporate headquarters is located at 224 West 30th Street, New York. Medscape is a part of WebMD Health Professional Network.[5] Medscape describes itself as "*the leading online global destination for physicians and healthcare professionals worldwide, offering the latest medical news and expert perspectives; essential point-of-care drug and disease information; and relevant professional education and CME*."[6]

8. Defendant WebMD Health Corp. is an Internet Brands company incorporated in Delaware with a principal place of business in New York, New York, which disseminates health information to consumers, healthcare professionals, employers, and health plans through public and private websites, mobile device applications, and other health-focused publications. In addition to other websites on similar topics, WebMD operates www.WebMD.com., which targets consumers, and www.Medscape.com., which targets healthcare professionals. WebMD charges for advertising, webpage sponsorships, and other online products and services on its websites.

9. Defendant WebMD Health Corp.'s corporate headquarters is located at 395 Hudson Street, 3rd Floor, New York, NY 10014. Defendant WebMD, LLC's corporate headquarters is also located at 395 Hudson Street, 3rd Floor, New York, NY 10014.

10. Defendant MH Sub I, LLC dba Internet Brands (Internet Brands), has its corporate headquarters located at 909 North Pacific Coast Highway, 11th Floor, El Segundo, CA 90245.

[5] https://www.medscape.com/public/about (Accessed May 3, 2023)
[6] Id.

11. Defendant Healthcare Performance Consulting has its corporate address located at 2321 Stockton Dr, Fleming Island, Florida, 32003.

12. Defendant CE Outcomes, LLC has its corporate headquarters located at 2101 Highland Ave. South #300A, Birmingham, AL 35205.

III. JURISDICTION AND VENUE

13. The action arises under the Federal False Claims Act ("FCA") 31 U.S.C. § 3732(a)

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 (Federal Question) and 31 U.S.C. § 3732(a) (False Claims Act), the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

15. To Relator's knowledge there has been no statutorily relevant public disclosure of the "*allegations or transactions*" in this Complaint, as those concepts are used in 31 U.S.C. § 3730(e), as amended by Pub. L. No. 111- 148, § 10104G)(2), 124 Stat. 119, 901-02. The public disclosure jurisdictional bar applies only when a complaint is "based upon" publicly disclosed information, 31 U.S.C. § 3730(e)(4)(A).

16. The Relator, Elizabeth Saenger, PhD, is the original source of, and has direct and independent knowledge about the misconduct alleged herein, and that knowledge is independent of, and materially adds to, any publicly disclosed allegations or transactions relevant to her claims. Dr. Saenger has personally gathered all the documentation substantiating the allegations herein. Additionally, she will voluntarily provide all such information to the Government after the filing of this action together with a written disclosure statement setting forth and enclosing all material evidence and information she possesses, pursuant to the requirements of 31 U.S.C. §3730(b)(2).

17. Venue is proper in the Southern District of New York pursuant to 28 U.S.C. §§ 1391(b)-(c) and 31 U.S.C. § 3732(a) because the Relator is a citizen of the State of New York while the corporate headquarters of Defendants Medscape, Inc., WebMD, LLC, and WebMD Global LLC are all located in this district Furthermore, the Defendants regularly transacted significant business in this district, thus resulting in and because violations of 31 U.S.C. §§ 3729 et seq. alleged herein occurred within this district as well.

IV. WEBMD AND MEDSCAPE

18. WebMD is the most popular source of health information in the US for both physicians and the general public and is likely to dominate Google search results for almost any medical question one may have.[7] According to its editorial policy, WebMD promises to empower patients and health professionals with "*objective, trustworthy, and accurate health information*."[8] Ostensibly, WebMD verifies the qualifications of all medical professionals on the site; including health professionals, experts, editorial professionals and contributors with a specialty license. WebMD claims that health professionals, including those who write, review, and edit its editorial content "*undergo credential verification by a third party*."[9]

19. WebMD's consumer advertiser customers include pharmaceutical, biotechnical, medical device and consumer product companies, hospitals, and other similar entities. WebMD also sells advertising and sponsorships for its health professional-directed websites.[11]

20. In 2013, researchers combined data from the 2010 grant registries of 14 pharmaceutical and device companies, and published their results in the medical article, '**Medical**

[7] https://www.vox.com/2016/4/5/11358268/webmd-accuracy-trustworthy. (Accessed June 20, 2023).
[8] https://www.webmd.com/ (Accessed June 20, 2023).
[9] https://www.webmd.com/about-webmd-policies/about-what-we-do-for-our-users. (Accessed July 24, 2023).
[11] Id.

Communication Companies and Industry Grants', in the *Journal of the American Medical Association.*[12] Of the 6,493 recipients of more than $657 million grant awards from drug and device companies, WebMD, along with its daughter site Medscape, were the top recipients of industry dollars. [13] In addition to "… *offering the latest medical news and expert perspectives, essential point-of-care drug and disease information…*"[5], Medscape also serves as a medical market research firm[14], a provider of free CME[15] for healthcare professionals and a creator of custom CME in varied formats, along with research on their effectiveness, for manufacturers.[16] Medscape claims that it is the "*#1 website used by physicians for professional purposes on any device*" and "*85% of physicians use mobile devices for professional purposes*" (citing 'Manhattan Research Taking the Pulse® Global v12.0).[17]

21. Medscape and WebMD differ significantly, both legally and substantively, from 'online social network platforms and communications services' such as Facebook, Twitter (now 'X'), YouTube, Threads, Instagram and TikTok. Neither Medscape nor WebMD is an interactive computer service in the style of FaceBook or Instagram but, instead, WebMD and Medscape's services,

> "…*are intended for physicians and other healthcare professionals"*
>
> and,
>
> "…*information and tools that* (Medscape) *make*(*s*) *available through the Services are provided for educational and informational purposes only*.[18]

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[12] Rothman SM, Brudney KF, Adair W, Rothman DJ. Medical Communication Companies and Industry Grants. JAMA. 2013;310(23):2554–2558.
[13] Id.
[14] https://www.medscapemarketresearch (Accessed May 3, 2023).
[15] https://www.medscape.com/today. (Accessed May 3, 2023).
[16] https://www.medscape.org/global (Accessed May 3, 2023)
[17] Id.
[18] Medscape Network Terms of Use. https://www.medscape.com/public/termsofuse#:~:text=You%20agree%20to%20defend%2C%20indemnify,resulting%20from%2C%20or%20alleged%20to. (Accessed July 27, 2023).

22. Medscape does not 'just' provide medical news and CME programs but also influences 'expert perspectives' on the CME programs on behalf of the client that funded them. Medscape's 'reach' in this regard is huge: Medscape receives some 18.3 million total visits each month.[19] Unlike the classic interactive computer services, Medscape not only develops CME, but also distributes CME for other CME providers. Medscape partners with CE Outcomes and Healthcare Performance Consulting in the development of CME, oftentimes resulting in improper and misleading promotion.

23. WebMD's annual revenue is $705.0M.[20] In 2017, Internet Brands, a company owned by private-equity firm Kohlberg Kravis Roberts (KKR) agreed to purchase WebMD Health Corporation for approximately $2.8 billion.[21]

V. GOVERNMENT HEALTHCARE PROGRAMS

24. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 et seq., establishes the Health Insurance for the Aged and Disabled Program, also known as Medicare. The United States Department of Health and Human Services ("HHS") administers the Medicare Program through the Centers for Medicare and Medicaid Services ('CMS').

25. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 et seq., establishes the Medicaid program, a federally assisted grant program for the States. Medicaid is a joint Federal-State program that pays for medical assistance for individuals and families with low incomes and relatively few assets. Medicare (Part D), Medicaid, the Veteran's Administration, and other public health care plans cover prescription drugs.

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[19] https://www.similarweb.com/website/medscape.com/ (Accessed May 7, 2023).
[20] https://www.zippia.com/webmd-careers-146012/revenue/
[21] Chad Bray. The New York Times. July 24, 2017. https://www.nytimes.com/2017/07/24/business/dealbook/kkr-webmd-natures-bounty.html. (Accessed August 3, 2023).

26. TRICARE is a government-funded program that provides medical benefits to retired members of the Uniformed Services and to spouses and children of active duty, retired, and deceased members, as well as reservists who were ordered to active duty for thirty (30) days or longer. The program is administered by the Department of Defense and funded by the federal government. Veterans of the United States military receive insurance benefits ("VA Insurance") through the Veterans Health Administration, a component of the U.S. Department of Veterans Affairs.

27. The Federal Employees Health Benefits Program ("FEHBP") provides healthcare benefits for qualified federal employees and their dependents. Under the FEHBP, the federal employee is covered by private payer health insurance which is in turn subsidized in part by the federal government.

28. The Office of Workers' Compensation Programs ("OWCP") of the U.S. Department of Labor ("DOL") administers federal workers' compensation programs under four statutes: (1) the Federal Employees' Compensation Act ("FECA"), 5 U.S.C. §§ 8101 et seq.; (2) the Longshore and Harbor Workers' Compensation Act ("LHWCA"), 33 U.S.C. §§ 901 et seq.; (3) the Federal Black Lung Benefits Act ("FBLBA"), 30 U.S.C. §§ 901 et seq.; and (4) the Energy Employees Occupational Illness Compensation Program Act ("EEOIC") (also known as the "Beryllium Exposure Compensation Act"), 42 U.S.C. §§ 7384 et seq.

29. Together, the programs described above, and any other government-funded healthcare programs, are referred to herein as 'Government Healthcare Programs.'

30. Each of the named Plaintiff-States offers Medicaid coverage for both adults and for children.

VI. CONTINUING MEDICAL EDUCATION

31. To safeguard public health, most physicians, advanced practice nurses, physicians' assistants, and other prescribers must take continuing medical education ("CME" or education to maintain their expertise.[22,23,24] Participation in accredited continuing medical education helps these professionals meet requirements for the maintenance of licensure, maintenance certification, credentialing, membership in professional societies, and other professional privileges.[25]

32. It is of critical important to understand that the regulation of continuing education is intended to be a proxy for quality as it establishes a minimum set of quality standards.[26] The current regulation of continuing education attempts to ensure high quality learning for health professionals by targeting individual professionals through licensure, certification, and credentialing, and by targeting providers of learning activities through accreditation.[27]

33. While CME courses *can* discuss off-label uses of drugs, those discussions must be **truthful,** and they **must note that the FDA has not approved them**. T**hey must not be misleading**. These rules are in place to safeguard the health and safety of the American public, who are at the mercy of the healthcare professionals prescribing these drugs.

34. To decide whether a CME program is independent, the FDA will consider,

"*Whether individuals employed by the provider and involved in* ***designing*** *or*

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[22] Federation of State Medical Boards. Continuing Medical Education Board-by-Board Overview. https://www.fsmb.org/siteassets/advocacy/key-issues/continuing-medical-education-by-state.pdf (Accessed May 10, 2023).

[23] Online Continuing Education for Healthcare Professionals. Nursing Continuing Education Requirements by State. https://www.aaaceus.com/state_nursing_requirements.asp (Accessed May 10, 2023).

[24] American Association of Physicians Assistants. CME requirements for certification maintenance. https://www.aapa.org/CME-central/CME-faqs/ (Accessed May 10, 2023).

[25] Accreditation Council for Continuing Medical Education. Why Accredited CME Matters. https://www.accme.org/why-accredited-CME-matters. (Accessed May 10, 2023).

[26] Institute of Medicine (US) Committee on Planning a Continuing Health Professional Education Institute. Redesigning Continuing Education in the Health Professions. Washington (DC): National Academies Press (US); 2010. 3, Regulation and Financing.

[27] Id.

> ***conducting scientific or educational activities are also involved in advising or otherwise assisting the company with respect to sales or marketing of the company's product***."[28] (Emphasis added).

VII. CONTINUING MEDICAL EDUCATION – OFF-LABEL PROMOTION

35. Unlawful off-label drug promotion has been the subject of significant health care, fraud enforcement efforts by the United States Department of Justice (DOJ) and the States' attorneys general using FCA. The theory underlying these efforts is that, by promoting off-label uses that are not medically accepted, **the manufacturers caused pharmacies to claim Medicaid, Medicare, and Veteran's Administration payment for drugs used in ways that are not covered by these governmental entities**. Most, if not all, state Medicaid programs exclude coverage for drugs that are used for off-label indications that are not medically accepted. Such use can waste Medicaid funds on ineffective treatments.[29]

36. One study by Qureshi et al. found that off-label marketing by drug companies was one of the most common causes of Medicaid fraudulent claim investigations.[30] These researchers,

> "*…identified 56 successfully concluded Medicaid FCA investigations associated with $5.5 billion in financial recoveries, with almost all of the recoveries occurring since 2006.* ***The most pervasive allegations involved billing fraud and off-label marketing by pharmaceutical manufacturers: $4.6 billion (85% of all Medicaid FCA recoveries) for 24 cases (43% of Medicaid FCA cases)****. The 2 largest*

[28] FDA. Guidance for Industry: Industry-Support for Scientific and Educational Activities. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/industry-supported-scientific-and-educational-activites. (Reference no. 2 at page 64097, pdf page 5)

[29] Centers for Medicare & Medicaid Services. Off-Label Pharmaceutical Marketing: How to Recognize and Report It. https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf (Accessed May 12, 2023).

[30] Qureshi Z.P., Liu Y., Sartor O., Chu Y.H., Bennett C.L. Enforcement actions involving Medicaid fraud and abuse, 1996-2009. Arch Intern Med. 2011;171(8):785–787.

recoveries (in dollars) involved pharmaceutical manufacturers. Eli Lilly paid $ 1.4 billion to resolve allegations of fraudulent marketing of pharmaceuticals. Purdue Pharma paid $634.5 million and pleaded guilty to misbranding charges that sales representatives had misled Medicaid providers to believe that oxycodone was nonaddictive."[31] (Emphasis added).

37. The FDA does not regulate doctors. After approval of a drug by the FDA, a doctor *may* lawfully prescribe it for both FDA-approved and non-FDA approved, or so-called 'off-label', uses.[32] Many drugs are commonly prescribed outside their approved indications (off-label), and most off-label use is not supported by sufficient evidence.[33] Whether characterized as either "*the standard of care*" or "*treacherous*," off-label use of FDA-approved drugs by physicians is an established aspect of the modern practice of medicine.[34] For some sensitive patient populations such as children or pregnant women, off-label drug use is a routine practice because many common treatments have never been tested in randomized clinical trials (RCTs) and have never been formally approved for these populations.[35,36] In some areas, for example pediatrics or oncology, a large part of the spectrum of therapeutic choices in routine care is off-label use.[37,38,39]

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[31] Id.

[32] United States v. Caronia, 703 F.3d 149 (2d Cir. 2012) at 153 (citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001); Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir. 1989); John E. Osborn, Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information, 10 Yale J. Health Pol'y L. & Ethics 299, 303 (2010) ("*Physicians may prescribe FDA-approved drugs . . . for any therapeutic use that is appropriate in their medical judgment*.")).

[33] Radley D.C., Finkelstein S.N., Stafford R.S.: Off-label prescribing among office-based physicians. Arch Intern Med 2006; 166: pp. 1021-1026

[34] Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51 (1998) at 56.

[35] https://www.fda.gov/consumers/consumer-updates/should-your-child-participate-clinical-trial. (Accessed May 11, 2023).

[36] https://www.fda.gov/consumers/womens-health-topics/women-clinical-trials. (Accessed May 11, 2023).

[37] Conti R.M., Bernstein A.C., Villaflor V.M., Schilsky R.L., Rosenthal M.B., Bach P.B.: Prevalence of off-label use and spending in 2010 among patent-protected chemotherapies in a population-based cohort of medical oncologists. J Clin Oncol 2013; 31: pp. 1134-1139.

[38] Frattarelli D.A., Galinkin J.L., Green T.P., Johnson T.D., Neville K.A., Paul I.M., et. al.: Off-label use of drugs in children. Pediatrics 2014; 133: pp. 563-567.

[39] Saiyed M.M., Ong P.S., Chew L.: Off-label drug use in oncology: a systematic review of literature. J Clin Pharm Ther 2017; 42: pp. 251-258.

38. The role of industry - specifically, pharmaceutical and device manufacturing companies - in underwriting the costs of CME, while widespread, is highly controversial.[40] Off-label promotion of drugs can often be found in courses for continuing medical education credits, many times where physicians themselves are doing the promoting of off-label uses.[41] While the FDA has traditionally differentiated between scientific and educational activities that are *industry-supported* and those that are *independent* and *non-promotional*[42] it does not regulate the presentation of scientific information in continuing medical education programs.[43] **However, for a program to be exempt from regulation, it must not be subject to any financial or other influence by medical product companies**.[44]

39. As described herein, most of Medscape's CME programs are not only sponsored by a pharmaceutical company whose drug is discussed or germane to the presentation but, more times than not, the authors and/or presenters are advisors and/or consultants and/or have received research grant(s) from the sponsors. In over half the whistleblower complaints analyzed by Kesselheim et al., "*Continuing Medical Education (CME) seminars were organized with speakers known to promote off-label uses*."[45] (Emphasis Added).

40. As evidence thereof, Ariana del Negro, in 2007 the Editorial Director of Cardiology at Medscape, said at a meeting at which Relator Elizabeth Saenger, PhD, was in attendance, "*The purpose of CME is off-label marketing*." This is the mindset at Medscape and has been for over 15

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[40] Changes Affecting Industry Funding of CME Programs. July 28, 2021. https://www.ethosce.com/blog/industry-funding-of-continuing-medical-education-programs/ (Accessed May 10, 2023).
[41] Noah L: Rebuttal: permission to speak freely. U Pa L Rev 162:248, 2013.
[42] Government Accountability Office (GAO) *Prescription Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses* Washington, DC: GAO; July2008. Available at: www.gao.gov/new.items/d08835.pdf. (Accessed May 10, 2023).
[43] Id.
[44] Id.
[45] Kesselheim AS, Mello MM, Studdert DM (2011) Strategies and Practices in Off-Label Marketing of Pharmaceuticals: A Retrospective Analysis of Whistleblower Complaints. PLoS Med 8(4): e1000431. doi:10.1371/journal.pmed.1000431.

years.

41. Stakeholders agree that professionals who take CME ('participants') do not detect bias in CME, but assert, on the basis of research, bias is nevertheless present in CME. For example, in 2020, Grundy et al. wrote within their article, '**Promotion or Education: A Content Analysis of Industry-Authored Oral Health Educational Materials Targeted at Acute Care Nurses**', [46]

> "*[T]he findings of this study call into question whether industry-authored materials are educational or promotional, which carries regulatory implications. Evidence of sponsorship bias affecting the focus, substantiation of claims and curation of expert recommendations suggests that* ***industry-authored educational materials have promotional intent and should be regulated as such***." (Emphasis Added)

42. In a large, prospective analysis, Kawczak et al.,[47] that,

> "[*t]he more subtle ways in which commercial support for CME creates bias cannot be easily measured, but every effort should be made to maintain and monitor scientific integrity.* ***There can be little question that industry desires to establish and maintain personal rapport with physicians and that industry's ultimate goal is commercial in nature***."[48] (Emphasis Added)

43. As discussed *infra*, the Accreditation Council for Continuing Medical Education (ACCME), regulates many CME providers using FDA Guidance.[4] The ACCME points to its 'Standards for Commercial Support',[3] a study it commissioned showing that physicians did not

[46] Grundy Q, Millington A, Cussen C, Held F, Dale CM. Promotion or education: a content analysis of industry-authored oral health educational materials targeted at acute care nurses. BMJ Open. 2020 Nov 27;10(11):e040541. doi: 10.1136/bmjopen-2020-040541. PMID: 33247018; PMCID: PMC7703418.
[47] Kawczak S, Carey W, Lopez R, Jackman D. The effect of industry support on participants' perceptions of bias in continuing medical education. Acad Med. 2010 Jan;85(1):80-4.
[48] Id.

detect bias[49] and asserts, *"**[I]ndustry is allowed no influence whatsoever over faculty or content***."[50] (Emphasis Added). In 2007, the U.S. Senate Finance Committee concluded that the ACCME guidelines may, in fact, be insufficient to prevent commercial bias within CME.[51]

44. Originally, the FDCA required drugs to be approved for *safety*, but not for *effectiveness*, before their introduction into the market.[52] As a result, even where the evidence did not support a manufacturer's therapeutic claims, the FDA still approved of drugs for general distribution as long as they were shown to be "safe under conditions proposed for their use in the labeling."[53] Not surprisingly, this led to a profusion of drug advertising that had "a deliberate intent to mislead."[54]

> *"A restriction on commercial speech satisfies the First Amendment if it directly advances a substantial government interest, (Central Hudson Gas & Elec. V. Public Serv. Comm'n., 447 U.S. 557 (1980)), is based on evidence of real harm and alleviates the harm to a material degree, (Edenfield v. Fane, 507 U.S. 761 (1993)), and is narrowly tailored to meet the desired ends. (Board of Trustees v. Fox, 492 U.S. 469, 480 (1989).*
>
> "*The physician is bombarded with **seductive advertising which fails to tell the truth, the whole truth, and nothing but the truth**. This often leads him into prescribing a new drug without adequate warning or information about its possible side effects and, indeed, without any solid clinical evidence that the drug is effective or is even as safe as the advertisers claim*."[55] (Emphasis Added)

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[49] Cervo RM, Gaines JK. Is there a relationship between commercial support and bias in continuing medical education activities? Commissioned by the Accreditation Council for Continuing Medical Education https://www.acCME.org/publications/there-relationship-between-commercial-support-and-bias-continuing-medical-education (Accessed May 10, 2023).

[50] McMahon G. Transparency in continuing medical education. The Lancet. 2018; 391: 2323-2324.

[51] Committee on Finance, United States Senate. Committee staff report to the chairman and ranking member: Use of educational grants by pharmaceutical manufacturers. Washington, DC: Government Printing Office; 2007.

[52] Knauer TE. The Regulation of Drugs on the Basis of Relative Effectiveness. 42 Food Drug Cosm. L.J. 323 (1987).

[53] Id.

[54] Id.

[55] Henry A. Waxman, A History of Adverse Drug Experiences: Congress Had Ample Evidence to Support Restrictions on the Promotion of Prescription Practices, 58 Food & Drug L.J. 299, 300 (2003) at 301–02.

45. The prescribing of FDA-approved drugs for off-label purposes is common but often not supported by strong evidence.[56] The off-label use of prescription drugs has been shown to be associated with more adverse drug events in adults than on-label use, especially when off-label indications are not backed by solid data.[57] In addition, off-label promotion, along with allegations of pharmaceutical company promotion of off-label promotion, has been the cause of major lawsuits and historically large out-of-court legal settlements.[58]

46. The most common form of off-label prescription involves the prescribing of currently available and marketed medications, but for a specific use (commonly known as an "indication" within the medical community) that has not received FDA approval.[59] Off-label prescribing can also apply to the use of a marketed medication in a patient population, dosage, or dosage form that does not have FDA approval.[60]

47. Continuing medical education must be independent of the companies which fund it.[61] However, it should be noted that the FDA also recognizes that "…*constraints on advertising and labeling, when applied to scientific and educational activities, can restrict the freedom of participants to discuss their data or express their views*."[62]

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[56] Radley DC, Finkelstein SN, Stafford RS. Off-label prescribing among office-based physicians. Arch Intern Med 2006;166:1021-1026.

[57] Eguale T, Buckeridge DL, Verma A, et al. Association of Off-label Drug Use and Adverse Drug Events in an Adult Population. JAMA Intern Med. 2016;176(1):55–63.

[58] Wittich CM, Burkle CM, Lanier WL. Ten Common Questions (and Their Answers) About Off-label Drug Use, Mayo Clinic Proceedings. (2012) 87;10:982-990.

[59] Wittich CM, Burkle CM, Lanier WL. Ten common questions (and their answers) about off-label drug use. Mayo Clin Proc. 2012 Oct;87(10):982-90. doi: 10.1016/j.mayocp.2012.04.017. Epub 2012 Aug 6.

[60] Id.

[61] Guenova M, Schäfer R, Palange P. Independent Continuing Medical Education (CME)/Continuing Professional Development (CPD) Must Deliver Unbiased Information. J Eur CME. 2019 Dec 12;8(1):1690321.

[62] FDA. Guidance for Industry: Industry-Support for Scientific and Educational Activities. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/industry-supported-scientific-and-educational-activites. (Reference no. 2 at page 64094, pdf page 2).

48. However,

> "*…discussions of unapproved uses, which can be an important component of scientific and educational activities,* ***are not permissible in programs that are or can be (because the provider is not functionally independent) subject to substantive influence by companies that market products related to the discussion***."[63] (Emphasis added).

49. The FDA will examine,

> "*…whether, and to what extent, a company is in a position to influence the presentation of information related to its products or otherwise transform an ostensibly independent program into a promotional vehicle."*[64] *"Off-label promotional statements could presumably constitute evidence of an intended use of a drug that the FDA has not approved*." (*Caronia*, 703 F.3d at 155 (citing 21 C.F.R. § 201.5)).

50. The FDA recognizes that **companies may influence the content of educational programs both directly and indirectly**.

> "***Directly, by being involved in the selection of speakers or in the treatment of topics. Indirectly, through the nature of the relationship between the company and the provider*** *(e.g., if the provider has reason to believe that future financial support from the company depends upon producing programs that promote the company's products.)*".[65] (Emphasis added).

51. The FDA considers several factors in evaluating programs and activities to determine whether industry-supported scientific and educational activities are independent of the influence of the supporting company.[4] Several of these 'factors' include the following:

- **Control of Content and Selection of Presenters and Moderators**

[63] Id.
[64] Id. at 3.
[65] Id.

"The FDA will look at whether the supporting company has engaged in scripting, targeting points for emphasis, or ***other actions designed to influence the program's content****.* (Emphasis added).

- **Disclosures**

"Including whether any unapproved uses of products will be discussed.

- **The Focus of the Program**

"The FDA will consider whether the intent of the company and the provider is to produce an independent and nonpromotional activity that is focused on educational content and free from commercial influence or bias.

- **Relationship Between Provider and Supporting Company**

"The FDA will consider whether there are legal, business, or other relationships between the company and the provider that could place the company in a position whereby it may exert influence over the content of the activity.

- **Provider Involvement in Sales or Marketing**

"The FDA will consider whether individuals employed by the provider and involved in designing or conducting scientific or educational activities are also involved in advising or otherwise assisting the company with respect to sales or marketing of the company's product."

"[*T]he agency will consider whether any complaints have been raised by the provider, presenters, or attendees regarding attempts by the supporting company to influence content.*"[66]

52. In addition to prohibiting manufacturers from directly marketing and promoting a product's unapproved use in a misleading, untruthful, and/or false manner, Congress and the FDA have acted to prevent manufacturers from employing **indirect methods** to accomplish the same

[66] Id. at 64099.

end. For example, the FDA regulates two of the most prevalent indirect promotional strategies: (A) manufacture dissemination of medical and scientific publications concerning the off-label uses of their product; and (B) **manufacturer support for CME programs that focus on misleading, untruthful, and false off label uses**.

53. Off-label marketing can harm patients, third-party payors, competitor manufacturers, and researchers and clinicians in multiple ways, including.[67]

- Prescription of more expensive but less effective or even nonsensical treatments;
- Exposure of patients to adverse side effects from drugs and devices that have not been adequately tested for safety and effectiveness in treatment of a particular condition;
- Heightened rates of adverse effects that have been demonstrated to be substantially increased in off-label use in general,[68] particularly in children.[69]
- Increased harms to patients who receive treatments that are less effective in treating a particular condition;
- Increased out-of-pocket expenses for vulnerable patients who do not have insurance to help cover the costs
- **Misuse of funds from government programs such as Medicare and Medicaid to cover inadequately tested, more expensive, and less effective products, leading to funding shortfalls in programs established for patients in need.** (Emphasis added).

54. In 2008, Medscape, itself, posted on its web site, '**Off-Label Promotion, On-Target Sales**'[70] by Drs. Adriane Fugh-Berman and Douglas Melnick wherein these authors wrote,

> "*[A]llowing off-label promotion of drugs for untested, unproven benefits maximizes industry profits at the expense of public health" and, "****[C]ompanies that engage in***

[67] Van Norman GA. Off-Label Use vs Off-Label Marketing: Part 2: Off-Label Marketing-Consequences for Patients, Clinicians, and Researchers. JACC Basic Transl Sci. 2023 Mar 27;8(3):359-370.
[68] Eguale T., Buckeridge D.L., Verma A., et al. Association of off-label drug use and adverse drug effects in an adult population. JAMA Int Med. 2016;176:55–63.
[69] European Medicines Agency Evidence of harm from off-label or unlicensed medicine in children. October 2004. https://www.ema.europa.eu/en/documents/other/evidence-harm-label-unlicensed-medicines-children_en.pdf. (Accessed August 8, 2023).
[70] Off-Label Promotion, On-Target Sales - Medscape - Oct 01, 2008. https://www.medscape.com/viewarticle/704698_10. (Accessed May 7, 2023).

> ***off-label promotion should be heavily fined and their future marketing practices subject to increased scrutiny by regulatory agencies***." (Emphasis added).

VIII. THE REGULATORY/LEGAL ENVIRONMENT

55. Accredited continuing education must protect learners from commercial bias and marketing. Accredited education must be free of marketing or sales of products or services. Faculty must not actively promote or sell products or services that serve their professional or financial interests during accredited education.[71] As such, continuing medical education is subject to a strict legal and regulatory environment and is primarily governed by the Accreditation Council for Continuing Medical Education (ACCME), the 'Anti-Kickback Act', and the False Claims Act.

A. ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION (ACCME)

56. The ACCME is responsible for accrediting institutions that offer CME to physicians and other healthcare professionals.[72] The ACCME's mission is to assure and advance quality learning for healthcare professionals that drives improvements in patient care. According to the ACCME,

> "*The Standards for Integrity and Independence in Accredited Continuing Education are designed to ensure that accredited continuing education serves the needs of patients and the public, is based on valid content, and is* ***free from commercial influence.***"[73,74] (Emphasis added).

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[71] Accreditation Council for Continuing Medical Education. Standards for Integrity and Independence in Accredited Continuing Education. Published 2020. https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce (Accessed July 29, 2023).

[72] https://www.accme.org/resources/video-resources/about-accme.

[73] Accreditation Council for Continuing Medical Education. Standards for Integrity and Independence in Accredited Continuing Education. Published 2020. https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce (Accessed July 29, 2023).

[74] The Standards have been adopted by the following accrediting bodies representing multiple health professions: Accreditation Council for Continuing Medical Education, Accreditation Council for Pharmacy Education, American Academy of Family Physicians, American Academy of PAs, American Nurses Credentialing Center, American Osteopathic Association, Association of Regulatory Boards of Optometry's Council on Optometric Practitioner Education, Joint Accreditation for Interprofessional Continuing Education™.

57. The Standards are designed to, *inter alia*, to *"(c)reate a clear, unbridgeable **separation between accredited continuing education and marketing and sales***". (Emphasis added). The ACCME is committed to ensuring that accredited continuing education (1) presents learners with only accurate, balanced, scientifically justified recommendations, and (2) protects learners from promotion, marketing, and commercial bias.

58. The AACME Standards also state that,

> "*Many healthcare professionals have financial relationships with ineligible companies. **These relationships must not be allowed to influence accredited continuing education**. **The accredited provider is responsible** for identifying relevant financial relationships between individuals in control of educational content and ineligible companies and managing these to ensure they do not introduce commercial bias into the education. **Financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company***.[75] (Emphasis added).

59. 'Standard 2' of the ACCME's 'Accreditation Rules: Standards for Integrity and Independence in Accredited Continuing Education', which applies to all accredited continuing education, states unequivocally:[76]

- *Accredited continuing education must **protect learners from commercial bias and marketing***.
- *The accredited provider must ensure that all decisions related to the **planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company***.

[75] Id. at 6 of 8.
[76] ACCME. Accreditation Rules. Standards for Integrity and Independence in Accredited Continuing Education

- ***Accredited education must be free of marketing or sales of products or services. Faculty must not actively promote*** *or sell products or services that serve their professional or financial interests during accredited education.*
- *The accredited provider must not share the names or contact information of learners with any ineligible company or its agents without the explicit consent of the individual learner.*

60. In its '**Identifying and Resolving Conflicts of Interest in Continuing Medical Education - An Educational Resource for Implementing the ACCME Standards for Commercial Support**[SM],[77] the ACCME states,

> "*CME providers must obtain from the planners, speakers and authors disclosures of their financial relationships that are relevant to the content being considered or planned for the activity (SCS 2.1).This disclosure information is so important to the CME process that individuals who refuse to disclose relevant financial relationships are disqualified from having a CME role that will give them the opportunity to affect the development, management, presentation or evaluation of that CME activity (SCS 2.2).*

61. It must be noted that Medscape proudly states that it is "…***accredited with commendation*** *by the ACCME (Accreditation Council for Continuing Medical Education) as a provider of certified physician education.*"[78]

62. 'Accreditation with Commendation' is the highest level of accreditation offered by ACCME and is awarded to providers that demonstrate exemplary performance, including demonstrated compliance with all Core Accreditation Criteria and eight of sixteen commendation

[77] https://www.accme.org/sites/default/files/null/SCS%20Toolkit%202_344_Identifying_and_Resolving_COI_20120207.pdf

[78] https://help.medscape.com/hc/en-us/articles/360010468592-About-Medscape-Education#:~:text=Medscape%2C%20LLC%20is%20accredited%20with,provider%20of%20certified%20physician%20education. (Accessed August 20, 2023).

criteria.[79] The commendation criteria are divided into three categories: 'Achieves Outcomes', 'Addresses Public Health Priorities', and 'Enhances Skills and Performance'.[80]

63. The AACME Standards also state that,

> "***Accredited providers that choose to accept commercial support (defined as financial or in-kind support from ineligible companies) are responsible for ensuring that the education remains independent of the ineligible company and that the support does not result in commercial bias or commercial influence in the education.*** *The support does not establish a financial relationship between the ineligible company and planners, faculty, and others in control of content of the education*.[81] (Emphasis added).

64. Commercial bias in industry-funded CME is not obvious, and current tools for identifying bias[82,83] fail to identify covert marketing messages.[84] The few studies that examined subtle biases consistently found subjective information favoring sponsored drugs.[85,86,87,88]

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[79] https://accme.org/achieve-commendation. (Accessed August 20, 2023).
[80] Id.
[81] https://help.medscape.com/hc/en-us/articles/360010468592-About-Medscape-Education#:~:text=Medscape%2C%20LLC%20is%20accredited%20with,provider%20of%20certified%20physician%20education. (Accessed August 20, 2023).
[82] Barnes BE, Cole JG, King CT, et al. A risk stratification tool to assess commercial influences on continuing medical education. J Contin Educ Health Prof 2007; 27:234-240.
[83] Takhar J, Dixon D, Donahue J, et al. Developing an instrument to measure bias in CME. J Contin Educ Health Prof 2007; 27:118-123.
[84] Goodwin B, Lim HD, Butler J, Paglia D, Dempsey MT, O Connor B, Fugh-Berman A. Increase your Confidence in Opioid Prescribing: Marketing Messages in Continuing Medical Education Activities on ER/LA Opioids. Pain Physician. 2021 Aug;24(5):E529-E538.
[85] Jung J, Fugh-Berman A. Marketing messages in CME on binge eating disorder. J Am Board Fam Med 2020; 33:240-251.
[86] Meixel A, Yanchar E, Fugh-Berman A. Hypoactive sexual desire disorder: Inventing a disease to sell low libido. J Med Ethics 2015; 41:859-862.
[87] Bowman, MA. The impact of drug company funding on the content of continuing medical education. J Contin Educ Health Prof 1996; 6:66-69.
[88] Infeld M, Bell AM, Marlin C, Waterhouse S, Uliassi N, Fugh-Berman A. Continuing medical education and the marketing of fentanyl for breakthrough pain: marketing messages in an industry-funded cme module on breakthrough pain. World Med Health Policy 2019; 11:43-58.

B. REGULATION OF PRESCRIPTION DRUG SALES AND MARKETING AND THE FIRST AMENDMENT

65. The United States Food, Drug and Cosmetic Act ('FDCA') established the framework for regulation of, *inter alia,* the sales and marketing activities of pharmaceutical manufacturers in the United States, including the introduction of new drugs into interstate commerce.

66. WebMD writes in its Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act Of 1934 (For the fiscal year ended December 31, 2015),[89]

> "*Information on our Websites that promotes the use of pharmaceutical products or medical devices is subject to FDA and FTC requirements and enforcement actions, and information regarding other products and services is subject to FTC requirements. If either agency finds that information on our Websites violates regulations or guidance, it may take regulatory or judicial action against us or the advertiser or sponsor of that information.* ***State attorneys general may also take similar action based on their state's consumer protection statutes****. Areas of our Websites that could be the* ***primary focus of regulators include pages and programs that discuss use of a regulated product or that the regulators believe may lack editorial independence from the control of sponsoring pharmaceutical or device companies***.[90]

> "*The Federal Food, Drug, and Cosmetic Act, or FDC Act, and its implementing regulations* ***require that prescription drugs be approved by the FDA prior to marketing***. ***It is a violation to market, advertise or otherwise commercialize such products prior to approval***. *The FDA allows for preapproval exchange of scientific information, provided it is non-promotional in nature and does not draw conclusions regarding the ultimate safety.*[91]

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[89] https://www.sec.gov/Archives/edgar/data/1326583/000119312516484757/d78402d10k.htm. (Accessed August 20, 2023).
[90] Id. at 20.
[91] Id.

> "*Labeling **and advertising can be neither false nor misleading** and must present all material information, **including risk information**, in a clear, conspicuous and **neutral manner**.*[92]
>
> "*There are several administrative, civil and criminal sanctions available to the FDA for violations of the FDC Act or FDA regulations as they relate to labeling and advertising. Administrative sanctions include a written request that violative advertising or promotion cease and/or that corrective action be taken, such as requiring a company to provide to healthcare providers and/or consumers information to correct misinformation previously conveyed. **More serious civil sanctions include seizures, injunctions, fines and consent decrees**. Any of these enforcement measures could prevent a company from introducing or maintaining its product in the marketplace. **Criminal penalties for severe violations can result in a prison term and/or substantial fines. State attorneys general have similar investigative tools and sanctions available to them**.*[93] (Emphasis added).

67. In December of 2012 the Second Circuit held in a two-to-one decision that the First Amendment prevented the FDA from construing the FDCA in such a way that it prohibited *truthful* promotion of an FDA-approved drug for off-label use. *See,* United States v. Caronia, 703 F.3d 149 (2d Cir. 2012).

> "*The Second Circuit held that, to avoid infringing the First Amendment, the misbranding provisions of the Federal Food, Drug and Cosmetic Act (the "FDCA") must be construed 'as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs' where the off-label use itself is lawful. 703 F.3d at 168*." *Id.* at 149.

[92] Id at 21.
[93] Id.

68. In 2015 the U.S. District Court for the Southern District of New York granted a preliminary injunction to prevent an FDA enforcement action, holding that a drug manufacturer had a First Amendment right to circulate *truthful* and *non-misleading* materials promoting off-label use of a drug. *Amarin Pharma, Inc. et al v. United States Food & Drug Administration* (119 F. Supp. 3d 196 (S.D.N.Y. 2015)).

69. As such, this complaint by Relator, Elizabeth Saenger, PhD, will be limited to her knowledge and discovery of those pharmaceutical-sponsored programs on Medscape which present information regarding the sponsors' pharmaceutical products untruthfully, falsely and/or in a misleading off-label manner.

C. THE ANTI-KICKBACK ACT

70. Pursuant to the Anti-Kickback Act, 42 U.S.C. Section 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) for which payment is sought from any federally funded health care program, including Medicare, Medicaid, Tricare, and the Veterans Administration.[94] The Department of Health and Human Services Office of the Inspector General ('HHS-OIG') Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (1991) are unambiguous in offering a broad definition of the term "remuneration" as "anything of value in any form whatsoever".

71. Under the federal Anti-Kickback Statute, a company commits fraud when it offers financial incentives to use the company's products or services for which payment may be made under Medicare, Medicaid, or other federally funded healthcare programs. Companies may try to

[94] 42 USC 1320a-7b Criminal penalties for acts involving Federal health care programs. https://uscode.house.gov/view.xhtml?edition=2016&req=granuleid%3AUSC-2017-title42-section1320a-7b&f=treesort&num=0. (Accessed August 3, 2023).

disguise their medical kickbacks as legitimate payments, e.g, paying doctors inflated rates for speaking engagements. Even if there is a lawful basis for a payment, the financial arrangement may still be fraudulent if one purpose of the payment is to influence a doctor or other healthcare provider to use the company's products or services.

72. The Anti-Kickback Act is designed to, *inter alia*, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry. Every federally funded health care program requires every provider or supplier to ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in the United States.

73. Notably, the Anti-Kickback Act does not require a kickback scheme to succeed in generating new business (i.e., new patient prescriptions) for a violation to have occurred. *See* *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F.Supp.2d 654, 664-65 (S.D.Tex. 2013). A pharmaceutical company violates the Anti-Kickback Act if it "*offers*" a pharmacy a kickback "*to induce*" the pharmacy to "*recommend[] purchasing*" the company's drugs. 42 U.S.C. § 1320a-7b(b)(2). Herein, the pharmaceutical companies pay hundreds of thousands of dollars for the right to sponsor a CME program and Medscape, during the time when the Relator was there, paid their authors/presenters, between $3,000 and $5,000 for a 5,000-word CME, amounts surely to have increased in the past several years.

74. One common scheme has been for pharmaceutical companies to provide payments or other financial incentives in the form of '**research funding and unrestricted educational grants**' to induce viewers/participants to prescribe their drugs to patients.[95]

[95] Lexchin J, Bero LA, Djulbegovic B, Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. BMJ. 2003 May 31;326(7400):1167-70.

75. Medscape/WebMD violate the Anti-Kickback Act if it "*receives*" a kickback "*in return for ... recommending*" those drugs. *Id*. at § 1320a-7b(b)(1). Medscape violates the Anti-Kickback Act even if it only "*solicits*" a kickback in exchange for recommending drugs covered by government programs. Id.

76. Thus, **it is the kickback arrangement itself that constitutes the Anti-Kickback Act violation, not the success of the arrangement**. *See* *US ex rel. Kester v. Novartis Pharmaceuticals*, 23 F. Supp. 3d 242, (S.D.N.Y.2014 at 263). "***The illegal recommendations in question do not have to actually convince someone to purchase the drugs who would not have otherwise done so***." *Id.*

77. Both the FCA and Anti-Kickback Statute are intended to ensure that physicians' medical judgments are not compromised by improper financial incentives and instead are based on the best interests of their patients. The Anti-Kickback Act prohibits suppliers such as pharmaceutical manufacturers from compensating, in cash or in kind, "*anything of value in any form whatsoever*" when a purpose of the payment is to influence the provider's prescribing habits or to gain favor for its product over the product of any competitor.

> "*Penalties for violating the federal anti-kickback law include imprisonment, fines and exclusion from participating, directly or indirectly, in Medicare, Medicaid and other federal healthcare programs. Any determination by a state, federal, or foreign regulatory agency that any of our practices violate any of these laws could subject us to civil or criminal penalties and require us to change or terminate some portions of our business and could have a material adverse effect on our business*."[96]

[96] https://www.sec.gov/Archives/edgar/data/1326583/000119312516484757/d78402d10k.htm. (Accessed August 20, 2023).

D. FALSE CLAIMS ACT - 31 U.S.C. §§ 3729 ET SEQ. ('THE FCA').

78. The False Claims Act ("FCA") dates to the Civil War and was substantially amended in 1986, 2009 and 2010. The 1986 amendment was made to enhance the Government's ability to recover losses sustained because of pervasive fraud against the United States in federal programs. The 1986, 2009 and 2010 amendments created incentives for individuals to come forward with information about fraud against the Government without fear of reprisals or Government inaction and enable the use of private legal resources to prosecute fraud claims on the Government's behalf.

79. FCA §§ 3729(a)(1)(A) and (B) set forth FCA liability for any person who knowingly submits a false claim to the government or causes another to submit a false claim to the government or knowingly makes a false record or statement to get a false claim paid by the government. §§ 3729(a)(1)(C) sets forth liability for any person who "*conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G).*"

80. The FCA defines this scienter requirement, stating that a person acts "*knowingly*" when, "*with respect to information*," the person (1) "*has actual knowledge of the information*," (2) "*acts in deliberate ignorance of the truth or falsity of the information*," or (3) "*acts in reckless disregard of the truth or falsity of the information*."

81. Knowledge can be established without "*proof of specific intent to defraud*." §3729(b)(1) and (2). "***The government, and not the Relator, must have suffered the `injury in fact' required for Article III standing***." *See* United States ex rel. Milam v. University of Texas M.D. Anderson Cancer Ctr., 961 F.2d 46, 49 (4th Cir.1992); United States ex rel. Weinberger v. Equifax, Inc., 557 F.2d 456 (5th Cir. 1977), *cert. denied*, 434 U.S. 1035, 98 S.Ct. 768, 54 L.Ed.2d 782 (1978); United States ex rel. Truong v. Northrop Corp., 728 F. Supp. 615, 616-620 (C.D.Cal.

1989); *United States ex rel. Newsham v. Lockheed Missiles Space Co.*, 722 F. Supp. 607, 614-615 (N.D.Cal. 1989).

82. "*Where there is evidence of palpable injury to the entity on whose behalf and in whose name the suit is brought, it is superfluous to require that the relator be individually aggrieved*." *United States ex rel. Truong v. Northrop Corp.*, 728 F.Supp. 615 (C.D.Cal.1989) at 619 (footnote omitted); *see also United States ex rel. Stillwell v. Hughes Helicopters, Inc.*, 714 F.Supp. 1084 (C.D.Cal.1989). at 1098 ("*There is no constitutional prohibition to the relator's suing, under a statutory grant of standing, on the injury to the United States*."); 13A Charles A. Wright et al., Federal Practice and Procedure § 3531.13, at 76 (1984) ("*if Congress wishes, indeed, it can enact a qui tam statute to enable a private party to invoke the standing of the government to collect a civil penalty*").

83. "The FCA is an anti-fraud statute that '*may be enforced not just through litigation brought by the Government itself, but also through civil qui tam actions that are filed by private parties, called relators, `in the name of the Government*.'" *Kellogg Brown & Root Servs., Inc. v. U.S. ex rel. Carter*, ___ U.S. ___, 135 S.Ct. 1970, 1973, 191 L.Ed.2d 899 (2015), quoting 31 U.S.C. § 3730(b)(1).

84. The government remains the real party in interest in a FCA suit. "*Although qui tam actions allow individual citizens to initiate enforcement against wrongdoers who cause injury to the public at large, the Government remains the real party in interest in any such action*." *US ex rel. Kreindler v. United Technologies Corp.*, 985 F.2d 1148 (2d Cir. 1993); *see also Minotti v. Lensink*, 895 F.2d 100, 104 (2d Cir.1990); *United States ex rel. Milam v. University of Texas M.D. Anderson Cancer Ctr.*, 961 F.2d 46, 49 (4th Cir.1992) at 49. ("*We could not lightly conclude that*

the party upon whose standing the justiciability of the case depends is not the real party in interest.").

85. The False Claims Act, 31 U.S.C. §§ 3729, provides that anyone who violates the law is liable for a civil penalty in addition to three times the damages. On January 30, 2023, Department of Justice (DOJ) adjusted the FCA 2023 False Claims Act penalties.[97] Now, for violations assessed after January 30, 2023, civil False Claims Act penalties will range from $13,508 to $27,018.

86. The FCA has a liberal scienter requirement: "*no proof of specific intent to defraud is required*" to state a claim under it. 31 U.S.C. § 3729(b).

87. Inasmuch as they are claims of fraud, qui tam complaints filed under the FCA are subject to Federal Rule of Civil Procedure Rule 9(b). *US ex rel. Chorches v. American Medical Response*, 865 F. 3d 71 - Court of Appeals, 2nd Circuit 2017, citing *U.S. ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 26 (2d Cir. 2016); *Gold v. Morrison-Knudsen Co*., 68 F.3d 1475, 1476-77 (2d Cir. 1995). Rule 9(b) states, "*In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally*."

88. The *Chorches* court held that "*Despite the generally rigid requirement [of Rule 9(b)], allegations may be based on information and belief when facts are peculiarly within the opposing party's knowledge*," citing *Wexner v. First Manhattan Co*., 902 F.2d 169, 172 (2d Cir. 1990). "*Pleading on information and belief is a desirable and essential expedient when matters that are necessary to complete the statement of a claim are not within the knowledge of the plaintiff*

[97] 88 FR 5776.

but he has sufficient data to justify interposing an allegation on the subject." 5C C. Wright et al., Fed. Prac. & Proc. § 1224 (3d ed. April 2017 Update).

89. In cases where the alleged fraudulent scheme is extensive and involves "*numerous transactions that occurred over a long period of time, courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct*." *In re Cardiac Devices Qui Tarn Litigation*, 221 F.R.D. 318, 338 (D.Conn. 2004) at 333. *Pleading the specifics of thousands of claims would be "cumbersome, unwieldy, and would accomplish no purpose*." Id. at 338.

90. The Fifth Circuit has held that,

> "*[s]tanding alone, raw bills—even with numbers, dates, and amounts—are not fraud without an underlying scheme to submit the bills for unperformed or unnecessary work.* ***It is the scheme in which particular circumstances constituting fraud may be found that make it highly likely the fraud was consummated through the presentment of false bills***." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009). (Emphasis added).

91. Herein, Relator, Elizabeth Saenger, PhD, provides multiple examples which lead to a strong inference that off-label, untruthful, and/or false presentations would result in increased prescribing of the sponsors' pharmaceutical products leading to the submission of claims to the Government Healthcare Programs, the particulars of which, upon information and belief, are peculiarly within the pharmaceutical companies' knowledge.[98]

[98] The Chorches decision, at 89, held that "…the approach taken by the Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits… have overtly adopted a 'more lenient' pleading standard. Those courts have allowed a complaint that does not allege the details of an actually submitted false claim to pass Rule 9(b) muster by 'alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.' Grubbs, 565 F.3d at 190 (5th Cir. 2009); U.S. ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1172 (10th Cir. 2010) (adopting Grubbs standard); Ebeid ex rel. U.S. v. Lungwitz, 616 F.3d 993, 998-99 (9th Cir. 2010) (same); Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 156-57 (3d Cir. 2014) (same); Heath, 791 F.3d at 126 (D.C. Cir. 2015) (same); cf. Lusby, 570 F.3d at 854 (7th Cir. 2009) ('We don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit.'"

92. False Claims Act penalties are mandatory for each separate violation of the law. The False Claims Act is intended to address all fraudulent attempts to cause the Government to pay out sums of money or to deliver property or services. *United States v. Neifert-White Co*., 390 U.S. 228, 232 (1968).

93. Once a violation is established, a False Claims Act penalty is mandatory for each violation. Congress explained clearly that imposition of a False Claims Act forfeiture is automatic and mandatory for each claim which is found to be false. (S. Rep. No. 99-345, at 8, reprinted in 1986 U.S.C.C.A.N. at 5274). Based on the foregoing laws, this complaint is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. 3729, *et seq*., as amended.

94. By virtue of the acts described herein, Defendants knowingly aided, abetted, colluded, and conspired with pharmaceutical manufacturers and, thus, aided and abetted the presentation of false or fraudulent information to physicians, which thereby resulted in unjustified and unsubstantiated claims to the United States Government for approval and payment. More specifically, by virtue of the acts described herein, Defendants knowingly aided and abetted in the development and presentation of online CME programs heavily biased towards the private interest of pharmaceutical manufacturers, which directly led to increased prescriptions of the manufacturers' drugs by attending physicians leading to increased claims for payment by the Government through programs such as Medicare, Medicaid, the Veterans Administration and other federal and State agencies.

95. The Government(s), unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid, and continues to pay the claims for excessive prescriptions that would not be paid but for the Defendants' illegal conduct, collusion and conspiracy with pharmaceutical companies.

96. By reason of the Defendant's acts, pharmaceutical companies and their "consultants", "advisors" "directors", "officers", "partners", "employees", and/or "trustees" were, and are, able to promote their product(s) misleadingly, untruthfully, and falsely, often off-label, to medical prescribers resulting in prescriptions which damages the United States Government and its constituents in a substantial amount to be determined at trial. Additionally, the United States is entitled to the maximum penalty of up to $27,018 for each violation arising from Defendant's unlawful conduct alleged herein.

97. Unlawful off-label drug promotion has been the subject of significant healthcare, fraud enforcement efforts by the United States Department of Justice (DOJ) and the States' attorneys general using FCA. The theory underlying these efforts is that, by promoting off-label uses that are not medically accepted, the manufacturers caused pharmacies to claim Medicaid, Medicare, and Veteran's Administration payment for drugs used in ways that would not normally be covered by these governmental entities. Most, if not all, state Medicaid programs exclude coverage for drugs that are used for off-label indications that are not medically accepted. Such use can waste Medicaid funds on ineffective treatments.[99]

IX. FACTUAL ALLEGATIONS

A. RELATOR ELIZABETH SAENGER, PhD.

98. The Relator, Plaintiff Elizabeth Saenger, PhD, grew up in the Bronx, NY and has maintained her primary residence in Manhattan, NY, since May of 1997. She earned an AB from Barnard College with a double major in Psychology and the Program in the Arts. After earning a PhD in social psychology from Harvard University, she studied developmental psychology as a

[99] Centers for Medicare & Medicaid Services. Off-Label Pharmaceutical Marketing: How to Recognize and Report It. https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf (Accessed May 12, 2023).

postdoctoral fellow at the University of California at Berkeley and completed a two-year residency in clinical psychology in Key West, Florida. She has taught psychology as an adjunct assistant professor at Columbia University and served as the staff psychologist at a community mental health care center. She then enjoyed private practice as a consultant, freelance writer, and licensed psychologist. Before joining Medscape, she worked as clinical director for the federally funded Project Liberty program at Hamilton-Madison House in New York."

99. In 2004, Relator Elizabeth Saenger applied to be a Program Director (later called Editorial Director) at Medscape. After a three-month trial period to determine whether she could make a successful transition from academia to the business of medical education, the Relator became an editorial director later that year.

100. However, soon after joining Medscape, Relator Elizabeth Saenger began to notice that the figures Medscape used to advertise the effectiveness of its new educational products looked like they "*might be too good to be true*." In part, because of information vice president Dr. Martin Irvine inadvertently gave her, she was able to establish that the stellar statistics Medscape gave to its clients (pharmaceutical companies) and other parties were actually fraudulent.

101. Relator then convinced Dr. Irvine that the numbers were systematically exaggerated but he refused to correct them for investors, clients, and other interested parties. However, he asked her to write a summary of the fraud and announced at an Editorial Directors' meeting that Medscape would use a different method to compute statistics going forward.

102. While at Medscape, she complained to her supervisor, at least three Vice Presidents, and the Sarbanes-Oxley[100] compliance officer about multiple practices she believed, and believes,

[100] Responding to corporate failures and fraud that resulted in substantial financial losses to institutional and individual investors, Congress passed the Sarbanes Oxley Act in 2002. The Act contains provisions affecting corporate governance, risk management, auditing, and financial reporting of public companies, including provisions intended

are unethical, illegal, and/or dangerous for the public. The Relator complained to Sylvia Velez, the Sarbanes-Oxley compliance officer, about the fraudulent statistics Medscape was using, the collaboration between Medscape and pharmaceutical companies, and especially about the collusion between Medscape and BMS to promote Abilify at such a time when Medscape was promoting that drug for off-label uses. Ms. Velez told the Relator that what the Relator described was, "*horrible*," but said there was nothing Ms. Velez could do.

103. As Medscape became increasingly dominated by pharmaceutical clients, some editorial (education) staff became demoralized. The Relator once said to Helen Fosam, PhD, editorial director of rheumatology, that Dr. Fosam was lucky she wasn't in psychiatry because psychiatry was so corrupt. Dr. Fosam said, "*You'd be surprised [about rheumatology]*" and explained she had complained to Dr. Irvine, but to no avail.

104. On October 9, 2007, Kathryn Pucci, Vice President Editorial at Medscape, informed Dr. Saenger that Steven Zatz, MD, then Executive Vice President at WebMD, knew that the CE Outcomes data was "*fraudulent*" around the time of Medscape's "*summit meeting*." On November 9, 2007, Jennifer Brown, Medscape's liaison to CE Outcomes, informed Dr. Saenger, Dr. Zatz, Dr. Irvine, Spencer Reese of Sales, and others knew "*that the CE Outcomes data is fraudulent" and admits she was hired as "window dressing*."

105. On June 23, 2007, Dr. Irvine notified Dr. Saenger by email that CE Outcomes would change its procedures so it would no longer be falsifying the data in one of these two ways. However, he did not address the other way CE Outcomes falsified the data, or mention other problems raised in Dr. Saenger's email. This email remains within the possession of Dr. Saenger.

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to deter and punish corporate accounting fraud and corruption. https://sarbanes-oxley-act.com/ (Accessed May 10, 2023).

106. On September 17, 2007, Dr. Saenger was offered a separation and release agreement because she is "*hardworking, gets along well with people here…[but is] unhappy*." The agreement informed Dr. Saenger that she had 21 days (until October 8, 2007) to consider it.

107. On January 10, 2008, Relator Elizabeth Saenger, PhD, is 'interrogated' by Dr. Zatz, Doug Wamsley, Executive Vice President, General Counsel at Medscape, and Bonnie Klugman (former Vice President-Employment at WebMD's parent company, Emdeon.) Relator Elizabeth Saenger, PhD explained how CE Outcomes is "*fudging the data*" and how "*Medscape is colluding with pharmaceutical companies*" and why, in the case of BMS, this is a public health concern.

108. On March 7, 2008, Dr. Saenger was involuntarily terminated,[101]

> "*…as a result of …violation of company policy regarding communications with the media and disclosure of confidential information to third parties in breach of …agreements and obligations to Medscape*."

109. When the director of HR and the Executive Vice President of Professional Services offered Relator Elizabeth Saenger a separation and release agreement, she originally assumed they wanted to oust her because she had pointed out that Medscape was disseminating fraudulent statistics about the effectiveness of its programs. However, during the conversation she realized that these individuals were not so much concerned with what she had found out; rather, they were relieved she hadn't found out more information and were afraid she might discover more.

B. OVERVIEW OF THE WEBMD AND MEDSCAPE SCHEME

(1) THE 'TROJAN HORSE'

110. Medscape and its clients (pharmaceutical manufacturers) violate FDA Guidance in a way that demonstrates that their intent is not "*to produce an independent and nonpromotional*

[101] Because of the amount of time which has passed since the Relator's involuntary termination, she is not making a claim for wrongful termination or retaliation.

activity that is focused on educational content and free from commercial influence or bias",[102] but rather, prescriptions written by physicians.

111. The "Trojan Horse" scheme, as coined and described by Dr. Saenger, is a large-scale, systematic, and measurably effective method which enables companies, for a price, to bias CME in favor of their products. The scheme begins with Medscape showing or delivering pharmaceutical companies a 'Sales Deck' and ends when Medscape sells pharmaceutical manufacturers the right to have a third party (originally only CE Outcomes) develop material on their behalf for CME. As documented herein by the Relator, Elizabeth Saenger, in the 'Trojan Horse' scheme, after the market research company develops content, Medscape **secretly and seamlessly embeds that unsourced material in CME programs as if it were part of the programs.**

112. Physicians who take the programs do not realize that sections of the CMEs are often written on behalf of pharmaceutical companies by unidentified third parties. WebMD, through Medscape, LLC, is complicit in these activities and knowingly aids and abets the various pharmaceutical companies to increase the prescribing of those companies' pharmaceutical agents thus increasing profits for those companies and increasing the likelihood that these companies will continue to pay Medscape to promote their products. As a result, billions of inappropriate charges are made to the aforementioned 'Governmental Government Healthcare Programs'. This complicity has continued for more than fifteen years.[103]

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[102] Guidance for Industry. Industry-Supported Scientific and Educational Activities, at p. 68. https://downloads.regulations.gov/FDA-1992-N-0007-0005/attachment1.pdf. (Accessed May 13, 2023).

[103] Collusion with market research firm CE Outcomes started in 2004 with **Acute Ischemic Stroke Treatment: Use of Intravenous Tissue Plasminogen Activator**. (https://www.medscape.org/viewarticle/495185). This was a "test run" and not supported by a sponsoring company but was "developed and funded" by Medscape itself. The first commercially sponsored CME program with embedded materials was Pfizer's program, **A Primary Care Approach to Insomnia Management** (https://www.medscape.org/viewarticle/498167) which promoted 'indiplon', an investigational sleep agent that was never approved.

113. Using the 'Trojan Horse', Medscape may embed material on behalf of the supporter for a fee, as indicated in its confidential brochure, *Medscape Education.*[104] This material can consist of:

- Multiple-choice questions,
- Personalized learning programs,
- Planned change assessments,
- Change messages, and
- Simulations.

114. In addition, questions about the participant – demographic questions – can enable market researchers to see how variables of interest, such as prescribing, vary depending on a professional's location, years in practice, number of patients with the disorder of interest, and so on.

115. The Trojan Horse scheme violates both the FDA Guidance and ACCME Guidelines in multiple ways, including the issue of "*whether the intent of the company and the provider is to produce an independent and nonpromotional activity that is focused on educational content and free from commercial influence or bias*."[105]

116. Medscape sells manufacturers the ability to use its physician audience for market research, and the promotion of their products. Specifically, Medscape allows manufacturers to commission material tailored to the CME they buy.

117. This is in direct violation of the AACME Standards which state,

[104] Medscape, LLC, of WebMD. Medscape education – Online medical education distribution: General information, p.5. No date. http://img.medscape.com/pi/pdf/mecc_downloadable.pdf (Accessed 6-18-22)

[105] Id.

> "***Accredited providers that choose to accept commercial support (defined as financial or in-kind support from ineligible companies) are responsible for ensuring that the education remains independent of the ineligible company and that the support does not result in commercial bias or commercial influence in the education.*** *The support does not establish a financial relationship between the ineligible company and planners, faculty, and others in control of content of the education*.[106] (Emphasis added).

118. Material is often originally developed exclusively for Medscape by medical market research company/defendant, CE Outcomes, Inc. Later, Medscape created content, occasionally, in combination with CE Outcomes. Medscape also partners with Healthcare Performance Consulting,[107] and Pro-Change Behavior Systems, Inc.[108] While CE Outcomes focused on using CME to change physicians' intended behavior, these market research companies had distinctive ways to change behavior, and measure that change, usually 30-60 days after physicians completed a program.

119. Relator alleges that the Defendants have collectively engaged, aided, abetted and conspired to engage in a decade's-long fraudulent scheme in connection with promoting pharmaceutical company products through continuing medical education programs and vignettes, each developed, produced, written, and posted on-line to increase the prescribing of the pharmaceutical company's drugs by healthcare providers to get a false or fraudulent claim allowed or paid by the United States.

120. The members of the conspiracy are:

- Drug manufacturers

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[106] https://help.medscape.com/hc/en-us/articles/360010468592-About-Medscape-Education#:~:text=Medscape%2C%20LLC%20is%20accredited%20with,provider%20of%20certified%20physician%20education. (Accessed August 20, 2023).
[107] https://changingperformance.com/ (Accessed May 3, 2023)
[108] https://prochange.com/ (Accessed May 3, 2023)

- A trade group created by the drug manufacturers (the Opioid REMS Program Companies as discussed *infra*)

- Providers of CME programs, including Relator Elizabeth Saenger, PhD's former employer, Medscape, LLC, of WebMD, and several professional societies

- Healthcare Performance Consulting, which develops unapproved content to embed in CME, and analyzes the impact of CME on prescribing

- CE Outcomes which often develops CME content for Medscape/WebMD

121. The object of the conspiracy between Medscape, WebMD, CE Outcomes Healthcare Performance Consulting, and the various pharmaceutical companies discussed herein is to design and use CME program content to cause healthcare providers to prescribe the drugs from the trade group manufacturers.

122. To achieve the object of the conspiracy, the members:

- Survey prescribers to determine what factors ('barriers') keep them from prescribing the trade group's drugs.

- Create CME program content with false claims tailored to overcome those barriers.

- Utilizing the 'Trojan Horse' scheme, to embed multiple-choice questions in the CME to find out to what extent prescribers reject those false claims before (vs after) taking CME, and hence how effective the programs are.

- Survey a subset of prescribers who take the programs post-program to confirm that the CME programs have reduced barriers and changed prescribing or intended prescribing.

- Interview a subset of the surveyed prescribers post-program about whether, and how, they changed their prescribing.

- Measure long-term changes in intended prescribing or prescribing post-program.

123. As a result, patients are taking drugs that are not as safe or effective as alternative medications, are often more expensive than suitable or even better alternatives, and/or are being

used off-label, all of which results in higher payouts by the aforementioned 'Government Healthcare Programs'.

124. The government, the ACCME and healthcare practitioners at large and the public do not know that this practice is going on. If the government did know, it would not allow private pharmaceutical companies to influence CME, whose ultimate purpose is to educate healthcare professionals, and not to improve the private profits of pharmaceutical manufacturers so heavily.

125. For a fee, clients of Medscape can fund material from a third party and have it secretly embedded in the education in violation of the FDA's **Guidance on Industry-Supported Scientific and Educational Activities**.[4]

126. A 2006 conversation between Relator, Elizabeth Saenger, and her, then, immediate supervisor, Martin Irvine, PhD, is illustrative of the collusion between Medscape, owned by WebMD, and pharmaceutical companies.

127. AstraZeneca, at that time, sponsored a CME program titled, '**Beyond Mania: Recognizing and Managing Refractory Patients with Atypical Antipsychotics' (2005).**[109] This program, written by Michael Thase, MD, involved the promotion of AstraZeneca's Seroquel (quetiapine) for the treatment of bipolar depression. Dr. Thase is a psychiatrist specializing in mood disorders. When he wrote the program, he was (and still is) a Professor of Psychiatry at the University of Pittsburgh Medical Center, Pittsburgh, PA. He is an independent psychiatrist whom the Relator recruited to write this and several other CME programs.

128. Seroquel did not receive FDA approval to treat bipolar depression until October 2008. In this 2005 program, Dr. Thase writes, regarding quetiapine:

[109] https://www.medscape.org/viewarticle/517948. (Accessed August 20, 2023).

"*The unpublished preliminary findings from the second RCT* (randomized controlled trial)*, which was reported at a press conference held in late October 2005, (ref.) entirely confirmed those of the first study. The field eagerly awaits release of the full results of this study. With 2 unequivocally positive studies, the manufacturer is in position to seek FDA approval for quetiapine as the first monotherapy for bipolar depression*."

129. This language, in the program itself, indicates that quetiapine was then, in fact, off-label. Yet CE Outcomes, Inc., and Medscape promoted the off-label use of quetiapine, the supporter's drug, for bipolar depression. An embedded case, with question and answer is below:

Case 1

"A 24-year-old male waiter was treated a year ago for pacing at night and sleeping only 3-4 hours a night. Female customers at his restaurant had complained that he was overly flirtatious and making suggestive remarks. At that time, he had been very talkative and required frequent redirection. He was treated with an atypical antipsychotic and was seen at 3 months and 6 months follow-up. After 3 more months, he stopped taking his medication. His psychiatric history was significant for 1 episode of major depression when he was 19 and dropped out of college. He has no other medical problems. He now presents with depressive symptoms of at least 1 month duration."

Which of the following have demonstrated ***effectiveness*** *in the treatment of bipolar depressive episodes?* (Emphasis added).

- ○ Risperidone and olanzapine
- ◉ Olanzapine; olanzapine and fluoxetine combined; and quetiapine
- ○ Aripiprazole and olanzapine
- ○ Clozapine and risperidone

176. CE Outcomes and Medscape 'identified' the correct answer as, "*Olanzapine; olanzapine and fluoxetine combined;* ***and quetiapine***" even though quetiapine was, then, off-label

for bipolar depression. Dr. Thase did not have a quarrel with the answer selected here for, as he stated, in clinical trials, each of the drugs has, in fact, "*demonstrated effectiveness*", though quetiapine had yet received FDA approval.

177. However, Dr. Thase was troubled by the choices in next CE Outcomes, Inc./Medscape question from the second 'case' embedded in the program, listed below:

> **Case 2**
>
> "*LK is a 40-year-old former computer programmer who presents with auditory hallucinations, disordered thoughts, and poor concentration. He has had trouble getting along with family members and does not have friends that he relates to. He was diagnosed in his early twenties with schizophrenia and had been treated with an atypical antipsychotic as well as group therapy. He had a history of noncompliance with group therapy, where his attendance was poor. He does not drink alcohol. He has smoked 1 1/2 packs per day since he was 15 years old*.
>
> Which of the following would you consider in **treating this patient**? (Emphasis added).
>
> ○ Perphenazine
> ○ Olanzapine
> ◉ Quetiapine
> ○ Aripiprazole

178. Here, CE Outcomes and Medscape embedded the question and answer. However, this is an example of Medscape embedding false, misleading, and untruthful information directly into its CME because when Dr. Thase saw what had been added to his program, he told the Relator that what had been added to his program was wrong. Specifically, all four drugs listed as answer choices were effective in treating the patient in the vignette. The Relator brought the discrepancy between Dr. Thase and the opinion of Outcomes, Inc up with her supervisor, Martin Irvine, PhD, but, Dr. Irvine did not correct the problem.

179. Note the language within the fourth full paragraph within the 2006 email from Relator Elizabeth Saenger to her supervisor, Martin Irvine, PhD asking specifically why the answer as written by CE Outcomes differs "…*from the opinion of author who wrote the activity*.".

Saenger, Elizabeth 41

From: Saenger, Elizabeth
Sent: Friday, April 07, 2006 11:57 AM
To: Irvine, Martin
Subject: Outcomes, Inc questions

Hi Martin.

Attached are the materials for Outcomes, Inc.

Basically there are only a few issues, such as:

How big is the difference between participants and non-participants on posttest questions? Is it numerically bigger or smaller than the difference between participants and non-participants on the Outcomes questions? Is it statistically bigger or smaller?

According to Outcomes, "The Outcomes, Inc. CME Quality of Education Index™ measures differences between participants and non-participant diagnostic and therapeutic responses to case vignettes [my emphasis]." If so, how do CME posttest questions get mixed in the effect size? **Why doesn't Outcomes report an effect size for Outcomes questions and an effect size for posttest questions if it wants to report posttest question data?**

Also, why is the effect size you report comprised of 80% Outcomes questions and 20% CME posttest questions? Why not 90% Outcomes questions and 10% CME posttest questions or some other split? **What was the rationale for weighing the effect size the way you did?**

Also, Q3 of the Outrcomes questions has only 4 choices (Perphenazine, Olanzepine, Quetiapine, Aripiperazole) but Michael Thase, MD, the author of the CU says the correct answer is "all of the above." **What does Outcomes consider the correct answer and why does this differ from the opinion of the expert who wrote the activity?** Who decides at Outcomes what the correct answers are?

Outcomes says, "The average score for participants of *Beyond Mania: Recognizing and Managing Refractory Patients with Atypical Antipsychotics* was 91%, the average non-participant score was 70%, and the average difference between scores was 21%."" **Does average score refer to Outcomes questions, posttest questions, or a combination, and if it is a combination, how is the combination weighted?**

Elizabeth

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180. This represents yet another violation of the ACCME's Standard 2,

- "*Accredited continuing education must* ***protect learners from commercial bias and marketing***.
- *The accredited provider must ensure that all decisions related to the planning, faculty selection,* ***delivery****, and evaluation of accredited education* ***are made without any influence or involvement from the owners and employees of an ineligible company***.

181. In addition, this is in violation of the FDA's Guidance, Section (1) Control of Content and Selection of Presenters and Moderators[110] which states that "***The agency will consider whether the provider has maintained full control over the content of the program, planning of the program's content, and over the selection of speakers and moderators***."

182. In this present example, it was not the independent psychiatrist, Michael Thase, MD, Professor of Psychiatry, who is listed as the "author" of the presentation, who wrote the entirety of the program but, rather, CE Outcomes and Medscape who, by utilizing the 'Trojan Horse', embedded a question *they* wrote, promoting the sponsor's product.

183. In a matter involving the 'FDA Guidance for Industry: Changes to an Approved NDA or ANDA', the court in *Ignacuinos v. Boehringer Ingelheim Pharms. Inc*., 8 F.4th 98, 104 (2d Cir. 2021), held that "***Although the FDA's guidance is not binding on this Court, it fully comports with the plain meaning of the regulation, and we find it persuasive***) while the court in *Hope Medical Enterprises Inc. v*. Fagron Compounding Services, LLC et al. No. 2:19-cv-07748-CAS(PLAx), U.S D.C, C.D., California (2021), citing to *Ignacuinos*, held "***Because FDA***

[110] FDA. Guidance for Industry: Industry-Support for Scientific and Educational Activities at 64097. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/industry-supported-scientific-and-educational-activites. (Accessed May 13, 2023).

guidance documents "represent the agency's current thinking," courts have found them to be persuasive authority."

184. Medscape added a new twist to its involvement in sales or marketing in late 2004, even before the incident with Dr. Thase. Relator Elizabeth Saenger, PhD had just started working at Medscape as Editorial Director of Psychiatry when Medscape's CME model was changing, so she saw it evolve. Specifically, this subterfuge began when:

- Editorial Directors developed programs and sent then them for CME review.
- After a program was officially approved for CME, Editorial Directors sent it to CE Outcomes, the medical market research company, if the manufacturer had bought the program, "*with Outcomes*".
- Outcomes would develop content tailored to the program commissioned by the manufacturer, and often favoring the manufacturer's product, and send the content to Medscape.
- Editorial Directors would then embed the Outcomes text into the program in the indicated spaces;
- The program would be published with content the CME reviewer and author, likely, had never seen.

185. Note that this yet another violation of the ACCME's standards regarding "*…decisions related to the* ***planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company****"* in addition to violating the FDA's Guidance.

186. When a program was published, Medscape would often collect data on physicians who took the program, including their answers to questions about, for example, what drug they would prescribe to a hypothetical patient in a vignette. Participants would be directed to the manufacturer's drug through a series of questions and answers which allowed the manufacturer to

learn how physicians thought its drug stacked up against its competition.

187. CE Outcomes would then analyze the market research data and send Medscape a report. The Editorial Director would review it and Medscape would send it on to the manufacturer. Outcomes CEO and Co-Founder Linda Casebeer, PhD, describes the basis for marketing through CME in her article, '**What's ROI Got to Do With CME?**' which was distributed to Medscape Editorial Directors.

188. The program measured its effects on the physicians who took it by presenting an embedded case history and questions in the beginning or middle of the CME program and a comparable case with questions at the end. This method allowed market researchers to determine that (for example) after taking '**Helping the Hyperactive Child: When Autism Looks Like ADHD**',[111] 16.8% more participants (physicians who completed the program) said they would prescribe Risperdal to a child, age 3½, than said they would do so in the middle of the program even though the drug was not approved by the FDA, and was risky, for a child that young.

189. This particular circumstance is part of "*the scheme*" which makes it ***"highly likely (a) fraud was consummated through the presentment of false bills***." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009).

190. There are some issues about how CME choices translate into actual prescribing, and submission of invoices for payment by the Government Healthcare Programs, and a body of research exists on this topic. The Janssen-funded report on '**Helping the Hyperactive Child: When Autism Looks Like ADHD**,[112] discussed *supra*, shows the actual influence the Janssen-

[111] Helping the Hyperactive Child: When Autism Looks Like ADHD. https://www.medscape.org/viewarticle/556601. (Accessed May 13, 2023).
[112] Id.

sponsored Medscape program had on prescribing physicians. In an analysis of the report, which was co-authored by CE Outcomes and Medscape, the influence of the program can be appreciated by looking at the percentage of 'Pre-Participants', 'Post-Participants' and control group 'Non-Participants' would prescribe Risperdal, off-label, to a 3½ child with hyperactive behavior and symptoms of irritability and aggression.

191. This Janssen-funded CME program, '**Helping the Hyperactive Child: When Autism Looks Like ADHD'**,[113] together with a market research report about it, show the concrete effects of off-label marketing in CME.

192. Employing the "Trojan Horse', this Janssen program embeds several case histories, and multiple-choice market research questions, throughout the CME. This unsourced embedded material makes up 20% of the program. (1,348 words were created by CE Outcomes on behalf of the manufacturer, and 5,276 words were written by the author, not counting references, and boilerplate); again, violating the ACCME standards and FDA Guidance.

193. While 82.2% of 'Pre-Participants' and 82.1% of 'Non-Participants' would consider the use of Risperdal off-label to treat the hypothetical 3 ½ child, **an astonishing 96.0% of 'Post-Participants'**, those who read the Janssen-funded program on Medscape, would consider prescribing Risperdal to the child *despite it being unsafe*.

[113] https://www.medscape.org/viewarticle/556601 (Accessed May 13, 2023).

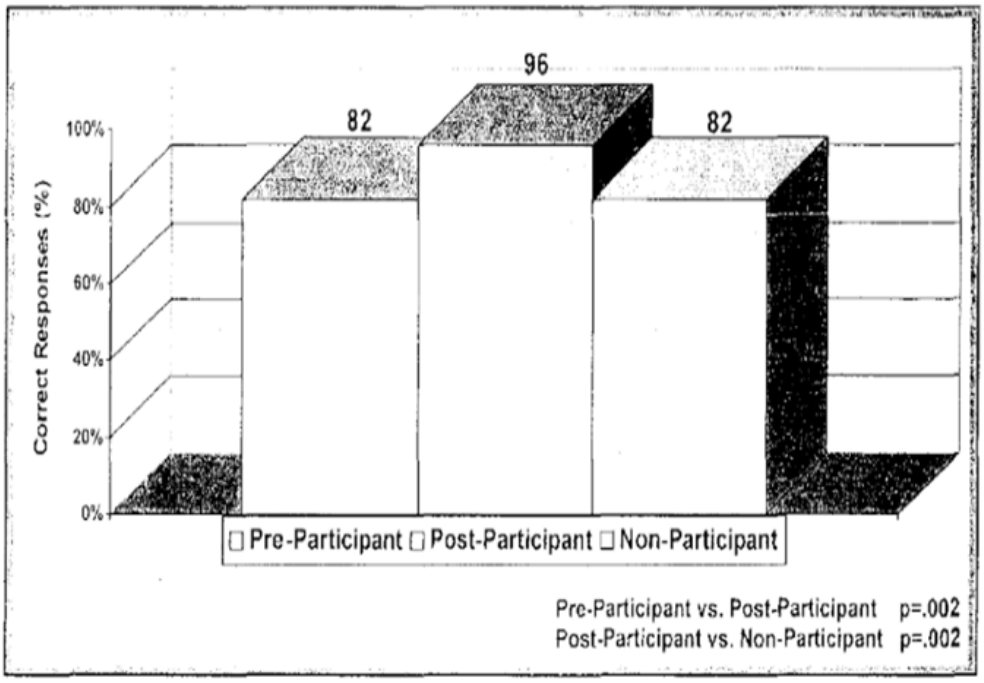
Case 1 Continued: Over the next few months, his hyperactive behavior has improved somewhat, but symptoms of irritability and aggression continue, and he has demonstrated occasional episodes of self injury.

Based on Case #1, which of the following would you consider for this patient? (select only one)

	Pre-Participant	Post-Participant	Non-Participant
Clonidine	15.8%	2.0%	16.8%
Naltrexone	1.0%	2.0%	1.1%
Amantadine	1.0%	.0%	.0%
Risperidone	82.2%	96.0%	82.1%

Pre-Participant n=101, Post-Participant n=101, Non-Participant n=95

Ninety-six percent of post-participants selected risperidone to treat persistent ADHD symptoms of irritability and aggression, even self injury, in a child with autism



194. However, this program increased the danger that physicians would prescribe Risperdal for very young children. **Risperdal is still off-label for children less than 5 years of age and its off-label promotion not only violated the corporate integrity agreement Janssen (Johnson & Johnson) signed on August 30, 2012, but also the FCA, the ACCME's Standards and FDA Guidance**. On that date, Janssen Pharmaceuticals, Inc., a Johnson & Johnson company,

announced a settlement and consent decree with 36 states and the District of Columbia regarding previously disclosed allegations related to promotional and marketing practices for its atypical antipsychotic prescription medication Risperdal.[114]

195. In a complaint filed in New York County Supreme Court, Attorney General Schneiderman charged that from 1998 through at least 2004, Janssen Pharmaceuticals engaged in deceptive and misleading practices when it marketed Risperdal, Risperdal Consta, Risperdal M-Tab and Invega for off-label uses.[115] Janssen agreed to pay approximately $181 million, an amount which has been previously accrued, as part of a consent decree to resolve state consumer protection law claims in the 36 states and the District of Columbia related to this matter.

196. As part of the settlement, Janssen reaffirmed it would not promote any of its atypical antipsychotics for off-label uses or make any false or misleading claims related to those products. The complaint charged that Janssen promoted Risperdal for unapproved uses, including dementia in elderly patients, schizophrenia and bipolar disorder in children and adolescents, depression, anxiety, obsessive compulsive disorder, conduct disorder, post-traumatic stress disorder, and Alzheimer's disease. Further, the complaint charged that Janssen concealed and misrepresented information regarding the side effects and efficacy of Risperdal thereby putting patients at risk. WebMD and Medscape were not fined for aiding and abetting Johnson & Johnson in their illegal promotion of Risperdal.

197. Further, Janssen's purchase of this Medscape CME in 2007 promoting Risperdal for this off-label use occurred after the period (1998 - 2004) covered in the 2012 settlement and its

[114] https://www.jnj.com/media-center/press-releases/janssen-pharmaceuticals-inc-announces-risperdal-consumer-protection-settlement-with-36-states-and-the-district-of-columbia. (Accessed July 30, 2023).
[115] https://ag.ny.gov/press-release/2012/ag-schneiderman-settles-181-million-deceptive-marketing-case-janssen (Accessed July 30, 2023).

off-label promotion violated the corporate integrity agreement Janssen (Johnson & Johnson) signed. Thus, Janssen and Johnson & Johnson are liable for the illegal, untruthful, and misleading off-label marketing they commissioned at Medscape, which, again, for a price, offered them the digital soapbox from which to promote their drug to children.

198. Further evidence of the impact which Medscape's sponsored presentation have on prescribing physicians can be ascertained by examination of the program, '**Testing Your Decision-making in Difficult Cases of MDD**' (Major Depressive Disorder)[116], initially published on November 15, 2015, although its content has not been edited nor changed since then. The program is still available to be accessed in 2023 although not for CME credit. This program was "…*supported by an educational grant from Takeda Pharmaceuticals U.S.A., Inc., and Lundbeck*"[117] to promote their drug, Trintellix (vortioxetine.)[118]

199. In this program, two 'Patient Simulation Cases' are made available for the participants to review and analyze. The results of this 2015 Virtual Patient Simulation showed that after watching this program, there was a one hundred (100) percent increase in the number of psychiatrists and primary care physicians who intended to prescribe vortioxetine.[119]

[116] Thase M. Testing Your Decision-making in Difficult Cases of MDD. Medscape CME & Education, 2015. https://www.medscape.org/viewarticle/852633. (Accessed May 13, 2023).

[117] Id.

[118] The author of this CME course was Michael E. Thase, MD, a Professor of Psychiatry at the Perelman School of Medicine at the University of Pennsylvania. In his 'disclosure', Dr. Thase discloses that he *"[S]erved as an advisor or consultant for, inter alia, Takeda Pharmaceuticals North America, Inc*." However, more important is the fact that Dr. Thase served both as faculty member for a CME program, which, by definition, is 'education' and at the same time and for the same program co-authored the market research analysis, e.g. marketing, in violation of the FDA's Industry-Supported Scientific and Educational Activities guidance.

[119] Lubarda J, Braun R, Thase M. Improving Management of Major Depressive Disorder Through Virtual Patient Simulation. Medscape CME & Education. 2016. https://img.medscapestatic.com/pi/edu/qrcode/posters/improving-management-of-mdd-through-virtual-patient-simulation.pdf (Accessed May 13, 2023).

200. More than nine million commercially insured Americans have been diagnosed with depression.[120] The Centers for Medicare & Medicaid Services' (CMS's) Chronic Condition data indicates that 18.4% of all Medicare fee-for-service beneficiaries had a diagnosis of depression in 2018[121] compared to 46.7% of Medicare beneficiaries under age 65 years, who were entitled to Medicare due to a qualifying disability.[122] Eleven (11) percent of veterans within the Veterans Administration reported elevated rates of depression.[123] In 2020, an estimated 66.0% U.S. adults aged 18 or older with major depressive episode received treatment in the past year.[124] This was a huge bonanza for Takeda and Lundbeck for a use – cognition in MDD – which the FDA declined to approve until 2018.[125] Again, it is not illegal for a physician to prescribe a medication off-label. However, it *is* illegal for a manufacturer, Takeda, within this sponsored Medscape CME course, to promote the use of vortioxetine to treat cognition issues.

201. The Relator has in her possession many similar key documents showing the 'Trojan Horse' in action including Sales Decks used to obtain business from pharmaceutical companies and the list of the first 84 CME programs which have been doctored. The 'Trojan Horse' scheme utilized by Medscape allows many different pharmaceutical companies to infiltrate the purchased

[120] Blue Cross/Blue Shield. https://www.bcbs.com/the-health-of-america/articles/two-million-commercially-insured-americans-diagnosed-major-depression-not-seeking-treatment. (Accessed May 13, 2023).
[121] Centers for Medicare and Medicaid Services - Office of Minority Health. Depression Disparities In Medicare Fee For Service Beneficiaries. https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Dwnld-DataSnapshot-Depression.pdf. (Accessed August 9, 2023).
[122] Access to Care among Medicare Beneficiaries With and Without Depression. https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Downloads/ATC_Depression_2017.pdf. (Accessed August 9, 2023).
[123] US Department of Veteran Affairs. Office of Research & Development. https://www.research.va.gov/topics/depression.cfm#:~:text=The%20team%20found%2011%20percent,12.8%20percent%20of%20non%2DVeterans. (Accessed August 9, 2023).
[124] National Institutes of Health. Major Depression. https://www.nimh.nih.gov/health/statistics/major-depression#:~:text=all%20U.S.%20adults.-,Treatment%20of%20Major%20Depressive%20Episode%20Among%20Adults,treatment%20in%20the%20past%20year. (Accessed May 13, 2023).
[125] https://www.takeda.com/en-us/newsroom/news-releases/2018/trintellix-cognition-snda-approval (Accessed May, 2023).

CME presentations with false and misleading information which has been shown to influence the prescribing habits of watching physicians.

202. These promotions include, but are not limited to, off-label, untruthful, misleading, and false statements within continuing education programs regarding, but not limited to, antidepressant medications, antipsychotic medications, attention-deficit/hyperactivity disorder medications, cholesterol, dyslipidemia, and hypertriglyceridemia medications and, perhaps most ominously, opioids. Medscape states that it is accredited by the ACCME "with commendation", as discussed *supra*. However, Medscape blatantly flouts ACCME's Standards at its own risk.

203. Medscape is repeatedly violating several of the ACCME's accreditation standards, and the FDA's Guidance, and interjecting 'commercial bias', 'marketing', and 'promotion' into their CME presentations, routinely plan the presentations, select the authors/presenters and deliver the programs in such a way as to promote the sponsor's drugs in a misleading, untruthful and false manner.

204. In addition, as discussed *infra*, there are multiple instances when a presenter does not disclose a financial arrangement with the sponsoring company within the Medscape program and, yet discloses such a financial arrangement elsewhere, typically with a peer-reviewed published medical article. This is a direct violation of one of the standards utilized by the ACCME not only for accreditation but also for 'accreditation with commendation' which Medscape boasts possessing. The impact of losing ACCME accreditation is well recognized by WebMD.

205. On July 10, 2006, Medscape released, '**Sustaining Wakefulness in Excessive Sleepiness: Consequence Prevention: Excessive Sleepiness: Shift Work and Shift Work Sleep Disorder**', "*supported by an unrestricted educational grant from Cephalon*."[126] The presenter is

[126] https://www.medscape.org/viewarticle/532398_3. (Accessed July 22, 2023).

Charles A. Czeisler, PhD, MD. No disclosure is made by Dr. Czeisler or by Medscape as to any financial competing interest despite the ACCME's requirement, stated here again, that,

> "***CME providers must obtain from the planners, speakers and authors disclosures of their financial relationships that are relevant to the content being considered or planned for the activity*** *(SCS 2.1).****This disclosure information is so important to the CME process that individuals who refuse to disclose relevant financial relationships are disqualified from having a CME role*** *that will give them the opportunity to affect the development, management, presentation or evaluation of that CME activity (SCS 2.2).* (Emphasis added).

206. However, also in 2006, Dr. Charles A. Czeisler was the last-named author of a study titled, '**Impact of extended-duration shifts on medical errors, adverse events, and attentional failures.**'[127] Therein, in the article's 'Conflict of Interest Statement', Dr. Czeisler disclosed that he not only received "*consulting fees from, or has served as a paid member of, scientific advisory boards for… Cephalon…*" but also "*received lecture fees* (from)*…Cephalon*" in addition to also receiving "*…clinical trial research contracts from Cephalon and …an investigator-initiated research grant from Cephalon*." **And, perhaps most egregiously, Dr. Czeisler and Medscape fail to disclose that he is "*…the incumbent of an endowed professorship provided to Harvard University by Cephalon*", as disclosed in the medical article of the same year.**

207. Unsurprisingly, Dr. Czeisler devotes seven or eight slides of his presentation, and some text, to promoting armodafinil (Nuvigil) then an off-label drug from Cephalon.

208. Two of the factors considered by the FDA in evaluating activities and determining independence between a sponsor and presenter is "*whether there was meaningful disclosure, at the time of the program, to the audience are,*

[127] Barger LK, Ayas NT, Cade BE, Cronin JW, Rosner B, Speizer FE, Czeisler CA. Impact of extended-duration shifts on medical errors, adverse events, and attentional failures. PLoS Med. 2006 Dec;3(12):e487.

- *The company's funding of the program;*
- *any significant relationship between the provider, presenters or moderators, and the supporting company (e.g., employee, **grant recipient**, owner of significant interest or stock).”*[4]

209. Thus, Medscape is, again, in violation of the ACCME standards and the FDA’s Guidance.

(2) JAZZ AND XYREM

210. Xyrem (sodium oxybate) is a central nervous system depressant now indicated for the treatment of cataplexy[128] (granted on July 17, 2002) or excessive daytime sleepiness (EDS) in patients with narcolepsy (granted on November 19, 2005, and then, on October 29, 2018, for children 7 years of age and older).[129]

211. The National Institutes of Health notes that this Schedule II drug presents risks even when used as prescribed. Therefore, as of August 24, 2015,

> “*Xyrem is available only through a restricted distribution program called the Xyrem REMS Program, using the central pharmacy that is specially certified. Prescribers and patients must enroll in the program*.”[130]

212. Note that this Medscape presentation was ‘broadcast’ on September 17, 2015, three weeks after the Xyrem REMS was released. The Xyrem REMS was in effect for three weeks and yet, despite being mandatory for the use of Xyrem, the REM was not mentioned once by the

[128] Cataplexy is a condition that brings on brief bouts of muscle weakness or paralysis. It can happen in people living with the sleep disorder narcolepsy.

[129] A controlled substance, Xyrem carries a ‘black box warning’, the “FDA’s most stringent warning for drugs and medical devices on the market. Black box warnings, or boxed warnings, alert the public and health care providers to serious side effects, such as injury or death.” https://www.drugwatch.com/fda/black-box-warnings/ (Accessed May 11, 2023).

[130] https://www.biospace.com/article/releases/jazz-pharmaceuticals-presents-long-term-safety-and-efficacy-data-for-xyrem-sodium-oxybate-in-pediatric-patients-with-narcolepsy-with-cataplexy/?s=95 (Accessed May 11, 2023).

presenters. Each of the three physician 'authors' of this presentation served as "*an advisor or consultant for Jazz Pharmaceuticals*" or *"(r)eceived grants for clinical research from Jazz Pharmaceuticals, Inc*." In addition to the three physician 'authors', Stacey J.P. Ullman, MHS, Scientific Director at Medscape Education served as 'Editor' and Robert Morris, PharmD, Associate CME Clinical Director at Medscape, LLC, served as 'CME Reviewer'.

213. Xyrem is **one of the three most common date rape drugs**, according to the US Department of Health and Human Services.[131] Side effects can include loss of consciousness, coma, or death. In addition, Xyrem can cause '*anterograde amnesia*', leaving victims unable to recall details of an assault. Finally, patients on Xyrem need to be monitored for abuse, dependence, and tolerance.[132] This level of surveillance is not required for safer, alternative treatments for narcolepsy, such as Provigil (modafinil), a Schedule IV drug, and cognitive behavior therapy for narcolepsy. In short, Xyrem presents many risks to young patients - risks not acknowledged in this 2015 Medscape CME[133]**, at a time when Xyrem was indicated for adolescents 17 years and older**.

214. In 2015, **when the promotion of this drug for children less than 17-years of age was off-label**, Jazz Pharmaceutical, Inc. (Jazz) decided to focus on promoting this drug off-label for youth because ***"[a]t this stage in the company's evolution, Jazz stock will be driven by Xyrem sales***,"[134] and for those sales, it needed to dominate the pediatric market. And to do that, it relied in no small manner upon the 'Medscape soapbox' which, for a fee, Medscape was happy to provide.

[131] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2713368/ (Accessed May 11, 2023).
[132] https://www.drugs.com/monograph/sodium-oxybate.html (Accessed May 11, 2023).
[133] https://www.medscape.org/viewarticle/850666 (Accessed May 11, 2023).
[134] https://seekingalpha.com/article/2965686-jazz-pharmaceuticals-is-undervalued (Accessed May 11, 2023).

215. One Jazz-funded CME program featured two cases: one of an adolescent and the other of an adult.[135] The program is authored by Richard K. Bogan, MD, who disclosed he had served Jazz as an advisor or consultant, speaker or a member of a speakers' bureau, and grant recipient. Stacey J. P. Ullman, MHS, Scientific Director, **Medscape, LLC** and Lynne Kolton Schneider, PhD Medical Writer, Boca Raton, FL, served as Editors while Nafeez Zawahir, MD, CME Clinical Director at **Medscape, LLC**, served as CME Reviewer. This program was released for CME on June 25, 2015, valid for credit through June 25, 2016, and still available for access in 2023, although not for CME credits.

216. The fictitious adolescent in the CME, 'Sarah', "…***a 16-year-old*** (female) *who presents to her primary care provider (PCP) with lack of concentration and daytime sleepiness*." Consequently, at the end of the program, Dr. Bogan writes:

> "*Currently, there are no drugs approved by the US Food and Drug Administration (FDA) for cataplexy in children.* ***The sleep specialist encourages Sarah (and her parents) to seriously consider [Xyrem]****, and recommends they speak with a counselor familiar with narcolepsy*."

217. Once again, while it is 'legal' for a sleep specialist (a physician) to prescribe Xyrem off-label for this child, it is NOT legal for the pharmaceutical company to promote the drug in an untruthful, false manner, or misleading, i.e., promoting the safety of the drug without any mention at all of the potential serious side-effects including loss of consciousness, coma, or death, and anterograde amnesia, leaving victims unable to recall details of a sexual assault.

218. In Medscape's **Narcolepsy: Case-based Guidance in Recognition and Management**[136], "…*made possible, in part, by a grant from Jazz Pharmaceuticals*", published on

[135] https://www.medscape.org/viewarticle/837966 (Accessed May 12, 2023)
[136] https://www.medscape.org/viewarticle/827903 (Accessed May 12, 2023).

July 11, 2014, for credit through 2015 and still accessible to be reviewed in 2023, many side effects, including serious ones, for amphetamines and methylphenidate are listed. It adds, "*[a]bout one third of patients may develop tolerance [to these drugs]*." In **contrast, few side effects, and no serious ones, are attributed to Xyrem despite** the sobering side effects described above. Further, the risk of abuse and dependence with Xyrem is omitted entirely.

219. Facing the Challenges in Narcolepsy Management: Issues and Answers,[137] also "…*made possible, in part, by a grant from Jazz Pharmaceuticals*", published July 25, 2013, and still available to be read in 2023, presents by far the clearest, and most extreme, example of advocacy for the off-label use of Xyrem. The key conversation begins at 14:51 of the last section of the program. It appears to be sparked by the moderator's assertion that some "*pediatric sleep specialists*" are using Xyrem off-label. The presenters state how Xyrem improved the quality of life ("*which is huge*") for their young patients and recommend its usage.

220. The presenters of this Jazz Pharmaceuticals presentation are Thomas Scammell, MD, a "*consultant*" to Jazz Pharmaceuticals, Inc.; Richard Bogan, MD, who has received "*grants and research support from Jazz Pharmaceuticals*" in addition to being a "*consultant*" to Jazz and on its 'Speaker's Bureau"; Suresh Kotagal, MD, MBBS, who "..*has nothing to disclose*" in the way of financial relationships; and, Emmanuel Mignot, MD, PhD, who has also disclosed having receiving grants/research support from Jazz Pharmaceuticals, Inc.

221. In this Jazz Pharmaceuticals sponsored Medscape program, which is still accessible in 2023, the CME faculty deny having tolerance difficulties with Xyrem, but mention having a "*real problem*" with Provigil (modafinil). Perhaps this unspecified "*real problem*" is related to physicians' preference for Provigil. Jazz-funded research in CME found that for narcolepsy

[137] https://www.medscape.org/viewarticle/807895 (Accessed May 12, 2023).

patients with only severe sleepiness, 67% of physicians prefer Provigil (modafanil) or its closely related, newer form, Nuvigil (armadafanil), while only 13% prefer Xyrem.

222. One program, **Diagnosing and Treating Children with Narcolepsy**,[138] also "…*made possible, in part, by a grant from Jazz Pharmaceuticals*",[139] published September 24, 2015, and still available to be read in 2023**,** consists virtually entirely of a sequence of questions with specific feedback after each one. These questions find out, step by step, how physicians go through the process of diagnosing, and treating, a boy, age 5, and a girl, age 15. **It must be noted that Xyrem is off-label for patients less than 7-years of age and, at the time of its original publication, was also off-label for patients 15 years of age**.

(3) BRISTOL-MYERS SQUIBB AND ABILIFY

223. On September 26, 2007, the Department of Justice announced that Bristol-Myers Squibb and its wholly owned subsidiary, Apothecon, Inc., would pay more than $515 million to resolve allegations of illegal drug marketing and pricing.[140] Assistant Attorney General for the Civil Division and Acting Attorney General Peter D. Keisler stated at that time,

> "*The integrity of our health care system rests on physicians being able to make decisions based on the best interests of their patients…This settlement reflects the Justice Department's strong commitment to holding drug companies accountable for* ***devising and implementing fraudulent marketing*** *and pricing schemes that undermine that decision-making process at the expense of federal health care programs for the poor and the elderly*."

[138] https://www.medscape.org/viewarticle/848136#content=0_0. (Accessed May 12, 2023)
[139] The author of this CME presentation is Kiran Maski, MD, who disclosed that she received grants for clinical research from Jazz Pharmaceuticals, Inc.; the Editors are Stacey J.P. Ullman, MHS, **Scientific Director at Medscape Education** and Lynne Kolton Schneider, PhD, a "Freelance writer out of Boca Raton, Florida". The CME Reviewer as Robert Morris, PharmD, **Associate CME Clinical Director, Medscape, LLC**.
[140] https://www.justice.gov/archive/opa/pr/2007/September/07_civ_782.html (Accessed May 9, 2023).

> "*Second, the Government alleged that, from 2002 through the end of 2005, BMS* ***knowingly promoted the sale and use of Abilify****, an atypical antipsychotic drug,* ***for pediatric use*** *and to treat dementia-related psychosis,* ***both "off-label" uses****. The Food and Drug Administration has approved Abilify to treat adult schizophrenia and bipolar disorder but* ***has not approved the use of Abilify for children and adolescents*** *or for geriatric patients suffering from dementia-related psychosis."* (Emphasis added).

224. Medscape and WebMD significantly contributed to that "fraudulent marketing".

225. On the same day as the announcement by the DOJ of the settlement with BMS, September 26, 2007, over, *inter alia*, fraudulent marketing of Abilify, Medscape published '**Development and Treatment of Schizophrenia in a Pediatric Patient**'.[141] This program, 'authored' by Christoph U. Correll, MD,[142] and "*supported by an independent educational grant from Bristol-Myers Squibb*" promoted Abilify (aripiprazole) for **a 13-year-old** fictional boy. Aripiprazole did not get an indication for schizophrenia in adolescents ages 13 - 17 until **November 06, 2007**.

226. While BMS was fined over half a billion dollars for, *inter alia*, off-label and illegal promotion of Abilify, especially to adolescents, Medscape, allowing BMS to rhetorically stand upon its digital 'soapbox' to promote its drug, was not fined and continued to promote Abilify not only off-label but, more importantly, untruthfully and in a misleading fashion.

[141] https://www.medscape.org/viewarticle/563275. (Accessed May 9, 2023).
[142] Dr. Correll disclosed that he has served as a consultant to Bristol-Myers Squibb and served as an advisor to and lectured for BMS.

(4) SHIRE AND VYVANSE

227. Vyvanse (lisdexamfetamine dimesylate) is a central nervous system stimulant prescription medicine, manufactured by Shire Pharmaceuticals and approved for Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 to 12 years of age since **February 23, 2007**, and in adults in **2008**. Vyvanse is the sister drug to Adderall, also manufactured by Shire. Vyvanse was approved to treat moderate to severe binge eating disorder in adults on **January 30, 2015**. Vyvanse is not approved for use in children under 6 years of age with ADHD.[143]

228. Shire aggressively marketed Vyvanse, with campaigns to market the conditions before the drug was approved. In 2014, Shire was fined $56.5 million resolve civil allegations that it violated the FCA as a result of its marketing and promotion of several drugs, including Vyvanse.[144] Medscape was not fined at that time for aiding and abetting Shire in its violation of the FCA. Vyvanse has been a blockbuster for Shire for several years; when the drug received an indication for BED (Binge-eating disorder), Shire's chief executive predicted the approval would eventually add "*$200 million to $300 million to annual sales*."[145]

229. Shire gave Medscape a huge amount of ADHD business – so much so that for a while, 'Psychiatry' was divided into 'AHDH', managed by Priscilla Scherer, RN, and everything else, managed by Relator Elizabeth Saenger, PhD.

230. Shire promoted Vyvanse off-label for adolescents with ADHD for several years until the FDA gave the drug an indication for adolescents with ADHD. The Medscape programs promoting off-label use include:

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[143] Goodman DW. Lisdexamfetamine dimesylate (vyvanse), a prodrug stimulant for attention-deficit/hyperactivity disorder. P T. 2010 May;35(5):273-87.

[144] Shire Pharmaceuticals LLC to Pay $56.5 Million to Resolve False Claims Act Allegations Relating to Drug Marketing and Promotion Practices. September 24, 2014. https://www.justice.gov/opa/pr/shire-pharmaceuticals-llc-pay-565-million-resolve-false-claims-act-allegations-relating-drug. (Accessed May 13, 2023).

[145] https://www.reuters.com/article/us-shire-fda-approval-idUSKBN0L32E520150130. (Accessed May 13, 2023).

- **Successfully Diagnosing and Treating ADHD in Pediatric Patients**, posted November 27, 2007, and still accessible in 2023; "(*S)upported by an independent educational grant from Shire*"[146] involved discussions regarding "*AP…a* ***14-year-old girl*** *with a history of being treated in your office for ADHD and a reading disability*."

- **Pediatric ADHD: Guidelines for Initiating and Monitoring Treatment**, posted August 29, 2007, and still accessible in 2023; "(*S)upported by an independent educational grant from Shire*".[147]

- **ADHD in Childhood and Adolescence: New Evidence in Diagnosis and Treatment**, posted December 16, 2008 and still accessible in 2023; "(*S)upported by an independent educational grant from Shire*".[148]

231. Case histories lend themselves to promoting drugs because they can tell the story of a patient who tries one or more drugs that fail to help. The account can then end when the patient successfully uses the manufacturer's drug. Regardless of whether a drug does well in clinical trials, it can shine with the fictitious patient in the case history. Further, a single, vivid case can make more of an impression than just statistics. The case history is followed with a series of questions which funnel the reader towards the sponsor's drug.

232. Iwona Misiuta, PhD, MPA, joined the WebMD Professional Network as a scientific director when Relator Elizabeth Saenger, PhD, worked at Medscape. The Relator is in possession of a transcript involving a discussion between Dr. Misiuta and a 'Key Opinion Leader' (KOL),[149]

[146] https://www.medscape.org/viewarticle/565881. (Accessed May 13, 2023).
[147] https://www.medscape.org/viewarticle/561940. (Accessed May 13, 2023).
[148] https://www.medscape.org/viewarticle/585161. (Accessed May 13, 2023).
[149] According to the Pharma Marketing Network, 'key opinion leaders', or KOLs, are physicians who influence their peers' medical practice, including but not limited to prescribing behavior. Often KOLs are chosen more for their high prescribing habits than for their knowledge or other attribute that would enable them to influence their peers." (Pharma Marketing Network. The Pharma Marketing Glossary. https://www.pharma-mkting.com/glossary/ (Accessed March 11, 2023). Quite directly and bluntly, the marketing firm Watermeadow writes that the term 'KOL' is usually "*a convenient shorthand for those people – usually eminent, usually physicians –* ***who we co-opt***

Floyd Sallee, MD regarding their approach to a program they are developing to promote Vyvanse on Medscape.[150]

> "*IVANA [sic] MISHIUTA: I think that in terms of the patient profile, I don't know whichever way you want to approach it,* ***we did want to say that eventually*** *that they ...* ***you want to put them eventually on Vyvanse in the end***. *But do we want to try them with something initially and ...*
>
> *DR. SALLEE: Oh, yes, yes.... So yes,* ***we'll start out with, you know, an approved*** *... You know, I was thinking like a methylphenidate product, perhaps, and one that has a duration of action of, you know, six to eight hours, perhaps, like Concerta might have*."[151] (Emphasis added).

233. Dr. Sallee placed Vyvanse, an amphetamine, in the category of drugs that the American Academy of Child and Adolescent Psychiatry (AACAP) recommended as "*equally efficacious and…the best initial treatment of ADHD*." However, since the AACAP Recommendations[152] state that approved treatments be tried first, and Vyvanse was *not* approved at that time for adolescents, AACAP was *not* recommending Vyvanse as the "*best choice for initial*

into our development and marketing strategies". (Watermeadow (2006) Rethinking the 'KOL culture'. Next Generation Pharmaceutical Europe 4, http://www.ngpharma.eu.com/article/Rethinking-the-KOL-culture. (Emphasis Added). When acting as mediators for companies, KOLs provide medical information that supports pharmaceutical companies' sales and marketing goals". (Sismondo, S., Chloubova, Z. "*You're not just a paid monkey reading slides*": How key opinion leaders explain and justify their work. BioSocieties 11, 199–219 (2016)). The monetary value of pharmaceutical industry engagement of KOLs is best illustrated by data released under the US Open Payments program of the Physician Payments Sunshine Act, which show that in 2018 companies made payments to ~627,000 physicians totaling over $9.35 billion towards speaker and/or consulting fees or for the cumulative value of ownership interests. (Policy & Medicine. 2018 Open Payments Data Released https://www.policymed.com/2019/07/2018-open-payments-data-released.html. (Accessed (Accessed May 13, 2023).). These numbers are even more staggering when one considers that the entire NIH budget for 2018 was less than $40 billion. (National Institutes of Health Budget, https://www.nih.gov/about-nih/what-we-do/budget. (Accessed May 13, 2023). http://wame.org/ghost-writing-initiated-commercial-companies. (Accessed August 8, 2023).

[150] (Dr. Sallee - ADHD - Tape 1 - MEDSITE, page 10).

[151] Id.

[152] Pliszka S; AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry. 2007 Jul;46(7):894-921.

treatment of ADHD." Dr. Sallee was dissembling it to make it look like the funder's drug was FDA-approved, and AACAP-recommended.

234. After again grouping long-acting formulations of methylphenidate and Vyvanse together as "*efficacious*," Dr. Sallee concludes:

> "*If none of the FDA-approved agents result in satisfactory treatment of the patient with ADHD, AACAP Recommendation 8 (ref.) states that the practitioner should undertake a careful review of the diagnosis and then consider behavior therapy and/or the use of medications not approved by the FDA for the treatment of ADHD. These include the use of antidepressants and alpha 2-adrenergic receptor agonists*."

235. These words reinforce the earlier false impression that the manufacturer's drug is FDA-approved for adolescents by implying that the drugs discussed first are approved, and the drugs mentioned subsequently are different because they are not approved. This is misleading, false, and untruthful.

236. As with Vyvanse, Medscape programs tend to showcase positive aspects of the sponsor's drug, rather than rival drugs. There are several ways in which this is accomplished. For example, the 2007 program, **Successfully Diagnosing and Treating ADHD in Pediatric Patients**[153,154] with Floyd Sallee, MD, as the author, and "(*S)upported by an independent educational grant from Shire",* and still accessible in 2023, tells the story of a fictitious patient, 'AP' and 'Concerta', an approved drug made by the sponsor's rival, which does not work for 'AP'. However, the Shire's unapproved drug, Vyvanse, allows the patient (and Vyvanse) to shine.[155]

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[153] https://www.medscape.org/viewarticle/565881 (Accessed May 10, 2023).

[154] This program also uses a 'medical writer', Anne E. Zitron, PhD, a "Freelance Medical Writer" from City Island, New York.

[155] Vyvanse (lisdexamfetamine dimesylate) received FDA approval for the treatment of ADHD in adolescents on November 15, 2010, three years after this Medscape program. https://www.drugs.com/history/vyvanse.html

"*AP is a **14-year-old girl** with a history of being treated in your office for ADHD and a reading disability*.[156]

"Treatment with the medication lisdexamfetamine (Vyvanse) *30 mg/day began and AP agreed to reading interventions outside of school so that no one will know about her problems. Her parents explained that they could afford outside interventions for a limited time. By the time of AP's 3-month visit **she is up to 50 mg of lisdexamfetamine per day**. AP's behavior at home has improved and she states that she is having less trouble with schoolwork. AP has even agreed to remedial assistance at school. She now demonstrated an understanding and appreciation of her parents' financial burden. In addition, she explains that a friend of hers at school is dyslexic and she is willing to receive in-school reading assistance with some of her peers. AP's parents are less stressed and home life has improved*."[157]

237. By focusing on a fictitious patient who will get better on whatever drug the sponsor sells, a healthcare provider will likely promote the sponsor's drug successfully. Part of this effect is due to the power of the salience of a single patient (versus a raft of statistics) – an observation made by Nobel laureate Daniel Kahneman, and his research partner, Amos Tversky.[158]

238. After CME programs are written, Medscape sends them to CE Outcomes, Inc. This market research company then writes multiple-choice questions to be embedded in the programs, as described earlier. Unsurprisingly, this material dissolves the boundary between drugs such as Vyvanse, which are not approved, and approved alternatives, such as methylphenidate, just as Dr. Sallee does.

239. CE Outcomes placed its question about the best initial treatment for the fictitious adolescent shortly before Dr. Sallee addressed this issue. That way, CE Outcomes could find out

[156] https://www.medscape.org/viewarticle/565881. (Accessed May 11, 2023)
[157] https://www.medscape.org/viewarticle/565881_12. (Accessed May 11, 2023)
[158] https://www.ubs.com/microsites/nobel-perspectives/en/laureates/daniel-kahneman.html. (Accessed May 11, 2023)

how many physicians would prescribe each of four different drugs for adolescent ADHD before first Outcomes, and then Dr. Sallee, told them the (allegedly) correct answer.

240. The embedded market research question is,

> "*Which of the following psychopharmacologic treatments for ADHD is the best choice for initial treatment of AP*?"

241. The "*Correct Answer*" is identified as "*Methylphenidate or amphetamine*." The explanation given is,

> "*The methylphenidates or amphetamines have been shown to be equally efficacious and are the best choices for initial treatment of ADHD*."

242. Thus, the Answer Explanation from CE Outcomes groups methylphenidates (FDA-approved for adolescents) with amphetamines (Shire's drug, which is *not* FDA-approved for adolescents), and states both drugs are "*equally efficacious*" and "*best initial choices for treatment of ADHD*."

(5) AMARIN AND VASCEPA

220. Vascepa (icosapent ethyl [EPA]) was initially launched by Amarin Corporation in the United States after its approval in 2012 "*as an adjunct to diet and exercise and in combination with a statin for adults with high triglycerides with mixed dyslipidemia and coronary heart disease (CHD) or a CHD risk equivalent*."[159] "*High triglycerides*" were described as '**severe (≥500 mg/dL) hypertriglyceridemia**'.[160]

221. In 2013, an FDA Advisory Committee voted 9 to 2 *against* expanded approval of the drug, Vascepa. Amarin sought to promote Vascepa for the expanded indication of treating a

[159] FDA Advisory Panel Votes Against Recommending Approval of Vascepa sNDA. https://news.bloomberglaw.com/pharma-and-life-sciences/fda-advisory-panel-votes-against-recommending-approval-of-vascepa-snda. (Accessed May 13, 2023).

[160] Ballantyne CM, Braeckman RA, Soni PN. Icosapent ethyl for the treatment of hypertriglyceridemia. Expert Opin Pharmacother. 2013 Jul;14(10):1409-16.

much larger group of patients: those with lower triglyceride levels and cardiovascular disease who were already being treated with statins.

222. As 2015, Amarin Corporation sued the FDA arguing that the First Amendment gives the company the right to market its drug for this broader group of people despite the lack of regulatory approval and the lack of evidence of an outcomes benefit for patients.[161] Amarin filed suit against the FDA to "*ensure [the] ability to engage in truthful and non-misleading speech free from the threat of a misbranding action*".[162] At the center of their case was the "*truthful and non-misleading*"-ness of a single claim, which Amarin wished to distribute as part of its promotional materials: "*C: Supportive but not conclusive research shows that consumption of EPA and docosahexaenoic acid (DHA) omega-3 fatty acids may reduce the risk of coronary heart disease*."

223. The court granted Amarin's application for a preliminary injunction[163] and held that the FDA could not pursue misbranding sanctions against Amarin for statements that were **truthful** and **not misleading** and that the statements and disclosures proposed **were in fact truthful and not misleading**.[164]

224. As described herein, Amarin, through collusion with Medscape's continuing education courses, which it funded, assisted in producing, scripted, and used to objectively misrepresent the 'benefits' of Vascepa in both untruthful and misleading ways to induce participants of its *Medscape Education* courses to prescribe Vascepa off-label for conditions for which it was not approved. Behind these misleading promotions was the fact that Medscape, WebMD and Amarin's ultimate goal is "*commercial in nature*".

[161] Amarin Pharma, Inc. v. US FDA, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).
[162] Id. at 198.
[163] Id. at 237.
[164] Id.

225. On December 13, 2019, the FDA relented and approved the use of Vascepa as an adjunctive (secondary) therapy to reduce the risk of cardiovascular events among adults with elevated triglyceride levels **of 150 mg/dL or higher**. Patients **must also have** either established **cardiovascular disease** or **diabetes *and* two or more additional risk factors for cardiovascular disease.**

226. Beginning in 2011 and continuing until, at least, 2021, Amarin commissioned continuing education programs for prescribers from Medscape. These 'education programs' promoted off-label uses for Vascepa, Amarin's only product. The three most recent programs were published in 2022 and can be accessed for credit in 2023.

- **Cardiovascular Risk Reduction After Acute Coronary Syndrome: What Do the New Data Tell Us?** by P. Gabriel Steg. CME / ABIM MOC Released: 3/21/2023. Valid for credit through: 3/21/2024.[165]

- **Hot Off the Press from AHA Scientific Sessions 2022: Key Data and Clinical Conversations on Cardiovascular Risk Reduction** by P. Gabriel Steg, MD and Pam R. Taub, MD. CME / ABIM MOC / CE Released: 12/16/2022. Valid for credit through: 12/16/2023.[166]

- **Modern Cardiovascular Risk Reduction – A1C, Blood Pressure, and LDL-C...What Am I Missing?** by Michael Miller, MD and Lale Tokgözoğlu, MD. CME / ABIM MOC / CE Released: 5/16/2022. Valid for credit through: 5/16/2023.[167]

230. Vascepa has two indications: the first, granted in 2012, to lower *very high* triglyceride levels (≥500 mg/dL) and the second, granted in 2019, is for use **as an adjunct** to statin therapy in people with elevated triglyceride levels (≥150 mg/dL) **who must also have either established cardiovascular disease or diabetes and two or more additional risk factors for**

[165] https://www.medscape.org/viewarticle/989885. (Accessed May 13, 2023).
[166] https://www.medscape.org/viewarticle/985652. (Accessed May 13, 2023).
[167] https://www.medscape.org/viewarticle/973803. (Accessed May 13, 2023).

cardiovascular disease.[168]

233. Amarin-funded Medscape CME adds "*omega-3 fatty acids*"[169] in an unusual way to '**Exploring the Mechanism of Action of Omega-3 Fatty Acids and the Potential Impact on CVD Risk Reduction**', published July 30, 2013, and still accessible in 2023.[170] The course authors were Michael Miller, MD, Benjamin J. Ansell, MD and Harold E. Bays, MD.[171]

234. The 15th slide within this CME course appears to show the treatment recommendations from the '**National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III, or ATP III)**[172] report and is titled, '**ATP III Treatment Recommendations for Elevated TG Levels**'.

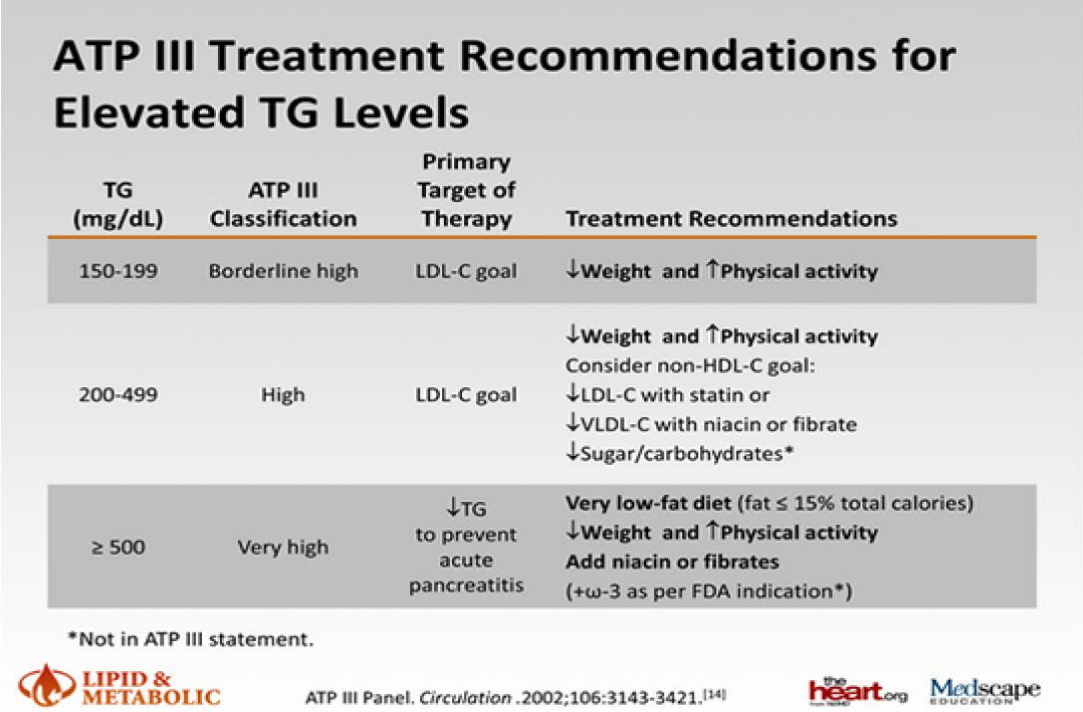
[168] FDA approves use of drug to reduce risk of cardiovascular events in certain adult patient groups. December 13, 2019. https://www.fda.gov/news-events/press-announcements/fda-approves-use-drug-reduce-risk-cardiovascular-events-certain-adult-patient-groups. (Accessed May 13, 2023)

[169] Omega-3s are sometimes referred to as "n-3s" and are present in certain foods such as flaxseed and fish, as well as dietary supplements such as fish oil. National Institute of Health. Office of Dietary Supplements. Omega-3 Fatty Acids. Fact Sheet for Health Professionals. https://ods.od.nih.gov/factsheets/Omega3FattyAcids-HealthProfessional/. (Accessed May 13, 2023).

[170] https://www.medscape.org/viewarticle/808286 (Accessed May 13, 2023).

[171] Michael Miller, MD, disclosed that he is also "an advisor or consultant to **Amarin**" in addition to having received grants for clinical research from **Amarin;** Benjamin J. Ansell, MD who didn't disclose any financial relationship with Amarin; Harold E. Bays, MD, who has served as an advisor or consultant to **Amarin** in addition to receiving grant funding from **Amarin**. The Editor for this CME presentation is Sarah Williams, PhD, Scientific Director, **Medscape, LLC** and the CME Reviewer is Nafeez Zawahir, MD, CME Clinical Director, **Medscape, LLC.**

[172] National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation. 2002 Dec 17;106(25):3143-421. PMID: 12485966.



ATP III Treatment Recommendations for Elevated TG Levels

TG (mg/dL)	ATP III Classification	Primary Target of Therapy	Treatment Recommendations
150-199	Borderline high	LDL-C goal	↓Weight and ↑Physical activity
200-499	High	LDL-C goal	↓Weight and ↑Physical activity Consider non-HDL-C goal: ↓LDL-C with statin or ↓VLDL-C with niacin or fibrate ↓Sugar/carbohydrates*
≥ 500	Very high	↓TG to prevent acute pancreatitis	Very low-fat diet (fat ≤ 15% total calories) ↓Weight and ↑Physical activity Add niacin or fibrates (+ω-3 as per FDA indication*)

*Not in ATP III statement.

LIPID & METABOLIC

ATP III Panel. *Circulation* .2002;106:3143-3421.[14]

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235. The title of this slide would lead the reasonable reader, medical or otherwise, to understand that that the material contained within the slide is, in fact, "*treatment recommendations*" from the Adult Treatment Panel III, whether contained within the cited reference or elsewhere.

236. This 'slide 15' is derived from Table VII.2-4 within the '**Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report**' at 3335[173] (below).

[173] National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation. 2002 Dec 17;106(25):3143-421. PMID: 12485966.

Table VII.2–4. Treatment Considerations for Elevated Serum Triglycerides

Serum Triglyceride Category	Special Treatment Considerations
Borderline High Triglycerides (150–199 mg/dL)	■ Primary goal: achieve LDL-C goal ■ Life-habit changes: first-line therapy for borderline high triglycerides – Body weight control – Regular physical activity – Smoking cessation – Restriction of alcohol use (when consumed in excess) – Avoid high carbohydrate intakes (>60% of calories) ■ Drug therapy: – Triglycerides in this range not a direct target of drug therapy
High Triglycerides (200–499 mg/dL)	■ Primary goal: achieve LDL-C goal ■ Secondary goal: achieve non-HDL-C goal: 30 mg/dL higher than LDL-C goal ■ First-line therapy for high triglycerides: TLC-emphasize weight reduction and increased physical activity ■ Second-line therapy: drugs to achieve non-HDL-C goal – Statins: lowers both LDL-C and VLDL-C – Fibrates: lowers VLDL-triglycerides and VLDL-C – Nicotinic acid: lowers VLDL-triglycerides and VLDL-C ■ Alternate approaches to drug therapy for lowering non-HDL-C – High doses of statins (lower both LDL-C and VLDL-C) – Moderate doses of statins and triglyceride-lowering drug (fibrate or nicotinic acid): **Caution:** increased frequency of myopathy with statins + fibrates
Very High Triglycerides (≥500 mg/dL)	■ Goals of therapy: – Triglyceride lowering to prevent acute pancreatitis (first priority) – Prevention of CHD (second priority) ■ Triglyceride lowering to prevent pancreatitis: – Very low-fat diet when TG >1000 mg/dL (<15% of total calories as fat) – Medium-chain triglycerides when TG >1000 mg/dL (can replace long-chain triglycerides in diet) – Institute weight reduction/physical activity – Fish oils (replace some long-chain triglycerides in diet) – Triglyceride-lowering drugs (fibrate or nicotinic acid): most effective – Statins: not first-line agent for very high triglycerides (statins not powerful triglyceride-lowering drugs) – Bile acid sequestrants: contraindicated—tend to raise triglycerides ■ Triglyceride lowering to prevent CHD: – Efficacy of drug therapy to prevent CHD in persons with very high triglycerides not demonstrated by clinical trials

237. The original information contained with the ATP III publication does not mention the use of *"+ ω-3 as per FDA indication*" (omega-3 as per FDA indication) as added to the bottom of Amarin/Medscape slide 15.[174] What ***is*** stated within ATP III in the right column, last row, under the subsection, 'Triglyceride lowering to prevent pancreatitis', amongst other recommendations is "*Fish oils (replace some long-chain triglycerides in diet*)" and "*Triglyceride-lowering drugs (fibrate or nicotinic acid): most effective*." There is no mention whatsoever of 'just' EPA (Vascepa).

[174] 'ω' is the lower-case Greek letter for 'omega'; ω-3 means omega-3.

238. Once again Vascepa consists solely of eicosapentaenoic acid (EPA); while it is an omega-3, it is *not* fish oil. But it is 'fish oils' "*which ATP III recommends for the treatment of Very High Triglycerides (≥ 500 mg/dL)*," *not* "*omega-3*" as added to slide 15 on the Medscape course. **Thus, Medscape's presentation of an edited version of this slide is misleading and is, in fact, false and untruthful**.

239. Presumably Amarin and/or Medscape added "+ *ω-3 as per FDA indication*" both to give the impression that the ATP III had recommended 'omega-3 fatty acids' for elevated TG levels and to notify participants that 'omega-3' had an indication for that purpose. This statement promoting "*omega-3*" as such a treatment based upon the ATP III Final Report recommendation is '**untrue, false, and misleading**.[175]

240. Furthermore, as readily observed, the ATP III Final Report states that evidence from "*[R]ecent clinical trials also suggest that relatively high intakes of n-3 fatty acids (1-2 g/day) in the form of fish, fish oils, or high-linolenic acid oils will reduce risk for major coronary events in persons* ***with established CHD***."[176]

241. The slide selected, and modified, for use within this Amarin-sponsored Medscape course, does not mention that the use of "+ *ω-3 as per FDA indication*", as inserted by Amarin

[175] Of note is the fact that the '2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines also do not mention also does not mention the use of omega-3 fatty acids other than to say, within **Table 9. Nonstatin Safety Recommendations**, "*If EPA and/or DHA are used for the management of severe hypertriglyceridemia, defined as triglycerides ≥500 mg/dL, it is reasonable to evaluate the patient for gastrointestinal disturbances, skin changes, and bleeding*."Stone NJ, Robinson JG, Lichtenstein AH, et al.; American College of Cardiology/American Heart Association Task Force on Practice Guidelines. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014 Jul 1;63(25 Pt B):2889-934 at 2910.

[176] As used herein, 'CHD' is the abbreviation for 'coronary heart disease"; 'CVD', or 'cardiovascular disease', is an umbrella term covering diseases of both the heart (cardio) and blood vessels (vascular) in the body. https://www.drugs.com/medical-answers/cardiovascular-disease-heart-disease-coronary-3515533/#:~:text=Cardiovascular%20disease%2C%20is%20an%20umbrella,pressure%20and%20peripheral%20artery%20disease. (Accessed May 13, 2023)

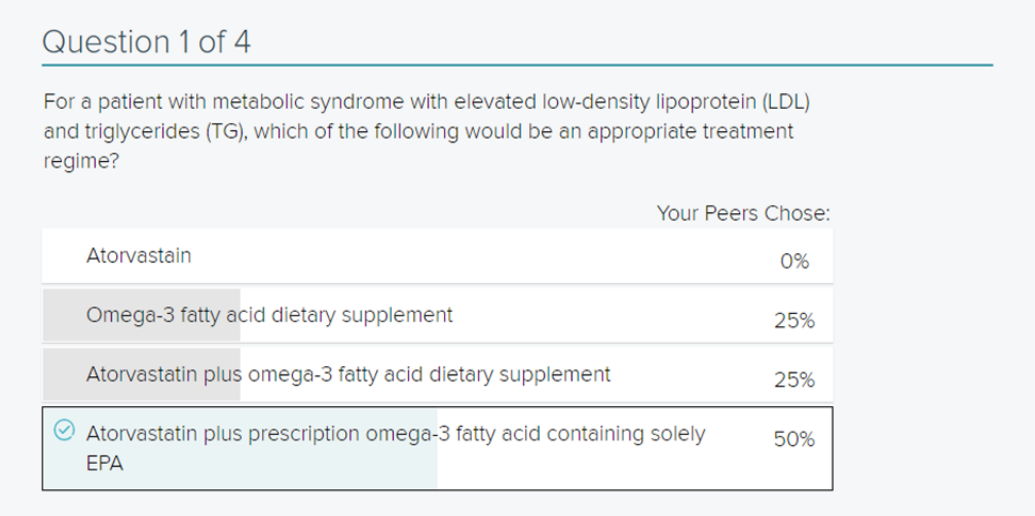
and/or Medscape, was limited to patients with "*established CHD*" "*as per FDA indication*". The slide thus **untruthfully and misleadingly promotes Amarin's product by misrepresenting the position of a respected authority**.

242. Relator Elizabeth Saenger, PhD has evidence of other Amarin-funded programs which also boast of more than a dozen potential benefits that omega-3 fatty acids might provide, making the presumed advantages of these substances salient.

243. In yet another Amarin-sponsored Medscape CME course, '**Back to Basics of Dyslipidemia: How Can Addition of EPA Reduce CV Risk**' (CME released April 13, 2016, valid for credit through April 13, 2017 and available to access in 2023)[177], four 'paid consultants' for Amarin (and other pharmaceutical companies) gave a presentation whose goal was to "…*increase clinicians' understanding of the impact of eicosapentaenoic acid (EPA) on mixed dyslipidemia and atherosclerosis and thereby enabling more effective treatment management for these high-risk patients*."[178]

244. Four answer choices are given for Question 1 of 4 and the correct answer is identified as, "*Atorvastatin plus prescription omega-3 fatty acid containing solely EPA*" and the reader is informed that 50% of fellow readers selected this answer as the correct answer.

[177] Borow KM, Mason RP, Nelson JR, Ross JL. Back to Basics of Dyslipidemia: How Can Addition of EPA Reduce CV Risk. Medscape CME & Education. 2016. https://www.medscape.org/viewarticle/861206. (Accessed May 13, 2023).
[178] Id.



245. Atorvastatin is a statin drug, product name Lipitor.[179] It is to be noted that the product insert for Vascepa at the time of this 2016 CME merely stated,

> **1 INDICATIONS AND USAGE**
>
> VASCEPA® (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.
>
> **Usage Considerations:** Patients should be placed on an appropriate lipid-lowering diet and exercise regimen before receiving VASCEPA and should continue this diet and exercise regimen with VASCEPA.
>
> Attempts should be made to control any medical problems such as diabetes mellitus, hypothyroidism, and alcohol intake that may contribute to lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogens) should be discontinued or changed, if possible, prior to consideration of TG-lowering drug therapy.
>
> Limitations of Use:
>
> The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.
>
> The effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

246. Importantly, the question from '**Back to Basics of Dyslipidemia: How Can Addition of EPA Reduce CV Risk**' asks, "*For a patient with metabolic syndrome with elevated*

[179] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf.

low-density (LDL) and triglycerides (TG), which of the following would be an appropriate treatment regime?"

247. The 'metabolic syndrome' is a group of five conditions that can lead to heart disease, diabetes, stroke and other health problems. Metabolic syndrome is diagnosed when someone has three or more of these risk factors[180,181,182]:

- High blood glucose (sugar)
- Low levels of HDL ("good") cholesterol in the blood
- High levels of triglycerides in the blood
- Large waist circumference or "apple-shaped" body
- High blood pressure

248. Note that the "*prescription omega-3 fatty acid containing solely EPA*" (Vascepa) **would not be indicated at all** for the hypothetical patient in Question number 1 based upon the product insert's indications for usage available in and about 2016 for nowhere within the question is the reader told that the hypothetical patient had "*severe (≥500mg/dl) hypertriglyceridemia*."

249. This an example of what the Relator refers to as the 'Trojan Horse scheme' utilized by Medscape and Amarin: sneaking information in as if it well-accepted and FDA approved when it's neither. It's false, untruthful, and misleading, designed to increase the prescribing of Vascepa to the financial detriment of Government Health Programs, commercial insurers and the American taxpayer.

[180] Reaven GM. Pathophysiology of insulin resistance in human disease. Physiol Rev. 1995 Jul;75(3):473-86

[181] Grundy SM. Hypertriglyceridemia, insulin resistance, and the metabolic syndrome. Am J Cardiol. 1999 May 13;83(9B):25F-29F.

[182] Meigs JB. Invited commentary: insulin resistance syndrome? Syndrome X? Multiple metabolic syndrome? A syndrome at all? Factor analysis reveals patterns in the fabric of correlated metabolic risk factors. Am J Epidemiol 2000;152:908-11.

250. As discussed *supra,* Vascepa received an amended indication in 2019. Vascepa is now indicated as follows:

----------INDICATIONS AND USAGE----------

VASCEPA is an ethyl ester of eicosapentaenoic acid (EPA) indicated:

- as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
  - established cardiovascular disease or
  - diabetes mellitus and 2 or more additional risk factors for cardiovascular disease. (1)
- as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. (1)

Limitations of Use:

- The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. (1)

251. Note that the amended indication in 2019 included the indication as

"*an adjunct to* ***maximally tolerated statin therapy*** *to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL)* ***and***

- ***established cardiovascular disease*** *or*
- ***diabetes mellitus <u>and</u> 2 or more additional risk factors for cardiovascular disease****.*
- ***as an adjunct to diet to reduce TG levels*** *in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia." (Emphasis Added)*

252. The answer provided within this 2016 Amarin-sponsored Medscape CME is false, untrue, and misleading for the following reasons:

- Vascepa was *only* indicated as an "*adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia*" in 2016.

- With the 2019 expanded indication, applicable inasmuch as the Medscape course has not been pulled down and is still available for review in 2023, Vascepa is indicated now "*as an adjunct to* ***maximally tolerated statin therapy***".
- The Question fails to tell the reader what dose of atorvastatin the hypothetical patient is taking: is it the "*maximally tolerated dose*"? The reader is merely told that the correct answer would include the statin atorvastatin.
- While the reader is informed that the hypothetical patient has the metabolic syndrome, one is left to guess which 3 or more components of the metabolic syndrome, discussed *supra*, are present.
- If the metabolic syndrome is diagnosed based upon the presence of (1) abdominal obesity, (2) high blood pressure and (3) high blood sugar levels, then Vascepa is not indicated at all and, again, the statement here is false, untrue, and misleading.
- *If* the metabolic syndrome diagnosis includes high blood triglycerides >150 mg/dL, then Vascepa *would* be indicated, under the expanded 2019 label change, **if, and only if**, the patient also had "*established cardiovascular disease*" (which is not mentioned within the question) *or "diabetes mellitus and 2 or more additional risk factors for cardiovascular disease*" which, again, the hypothetical patient within this question is not reported to have.

253. Therefore, under both the product insert in use in 2016 and the current product insert as of 2019, Vascepa is **not indicated** for the hypothetical patient in this question and the answer is a **false, untrue, and misleading promotion of off-label use.** As such, the given answer only serves to expand the population of people to whom Amarin can market its drug.

254. The Answer Explanation for this question states:

> Statins are effective LDL-lowering agents but have minimal effect on TG. Dietary omega-3 fatty acid dietary supplements contain a combination of EPA and docosahexaenoic acid (DHA), of which only the former is associated with TG lowering, while DHA can increase LDL. Therefore a statin plus a prescription omega-3 fatty acid is likely to yield the best results.

255. The first sentence of this 'answer' states, "*Statins are effective LDL-lowering agents, **but have minimal effect on TG***". (Emphasis Added). Bu**t this was patently untrue, false and misleading in 2016 and remains untrue, false and misleading in 2023**. Significant and dose-dependent reductions in triglyceride levels of 22 - 45% have been reported with all statins since, at least, 1996.[183,184, 185,186,187,188]

256. Medscape, itself, echoed these finding on its web site 7-years earlier, in 2009, with the publication of '**What Are the Effects of Statins on Triglycerides and What Are the Results of Major Outcomes Studies?**' by Michael Miller, MD wherein he stated:

> "*Although the most prominent effects attributable to statin therapy are its potent low-density lipoprotein cholesterol (LDL-C) lowering properties, **it is also well***

[183] Bakker-Arkema RG, Davidson MH, Goldstein RJ, Davignon J, Isaacsohn JL, Weiss SR, Keilson LM, Brown WV, Miller VT, Shurzinske LJ, Black DM. Efficacy and safety of a new HMG-CoA reductase inhibitor, atorvastatin, in patients with hypertriglyceridemia. JAMA. 1996 Jan 10;275(2):128-33.

[184] Schaefer EJ, McNamara JR, Tayler T, Daly JA, Gleason JL, Seman LJ, Ferrari A, Rubenstein JJ. Comparisons of effects of statins (atorvastatin, fluvastatin, lovastatin, pravastatin, and simvastatin) on fasting and postprandial lipoproteins in patients with coronary heart disease versus control subjects. Am J Cardiol. 2004 Jan 1;93(1):31-9.

[185] Sadeghi R, Asadpour-Piranfar M, Asadollahi M, Taherkhani M, Baseri F. The effects of different doses of atorvastatin on serum lipid profile, glycemic control, and liver enzymes in patients with ischemic cerebrovascular accident. ARYA Atheroscler. 2014 Nov;10(6):298-304.

[186] Catapano AL, Graham I, De Backer G, et al. 2016 ESC/EAS guidelines for the management of dyslipidaemias Eur Heart J, 37 (2016), pp. 2999-3058

[187] Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2019 Jun 25;73(24):e285-e350.

[188] Stein EA, Lane M, Laskarzewski. Comparison of statins in hypertriglyceridemia. Am J Cardiol. 1998;81(4A):66B-69B..

> ***established that statins significantly reduce*** *non-high-density lipoprotein cholesterol (non-HDL-C),* ***triglycerides (TG)****, and biomarkers of inflammation, most notably C-reactive protein (CRP). Overall,* ***statins reduce TG levels in the range of 10% to 20%*** *(Table), although it has been acknowledged that the higher the baseline TG level, the greater the TG-lowering effect*."[189] (Emphasis Added)

257. Thus, it was **absolutely untrue and false** to state that *"[s]tatins are effective LDL-lowering but have minimal effect on TG*" as Amarin/Medscape stated within the multiple-choice questions 'Answer Explanation'. This was a **blatantly untrue and false statement** put forth by the course panelists and approved by Medscape's editors and designed to direct the readers to deny or minimize the effectiveness of statins in reducing TG, and praise Vascepa for doing so. This is a violation of the FCA, ACCME'S standards and the FDA's Guidance.

258. This misleading and untruthful promotion of Vascepa resulted in needless and inappropriate payments by Medicare, Medicaid, the VA, and any other state and/or federal program responsible for the payment of drug costs for, in fact, less expensive and approved options such as fibrates are better. Fibrates will decrease this patient's TG level by 25-50%,[190,191,192] compared with a decrease of 10-50% for EPA. Since the Amarin/Medscape's patient's TG level is <500 mg/dL, fibrates will also decrease LDL-C ("bad cholesterol") by 10-30%. Fibrates will thus address both lipid problems in Amarin's-funded Medscape vignette and increase HDL-C ("good cholesterol") by 5 - 20%.

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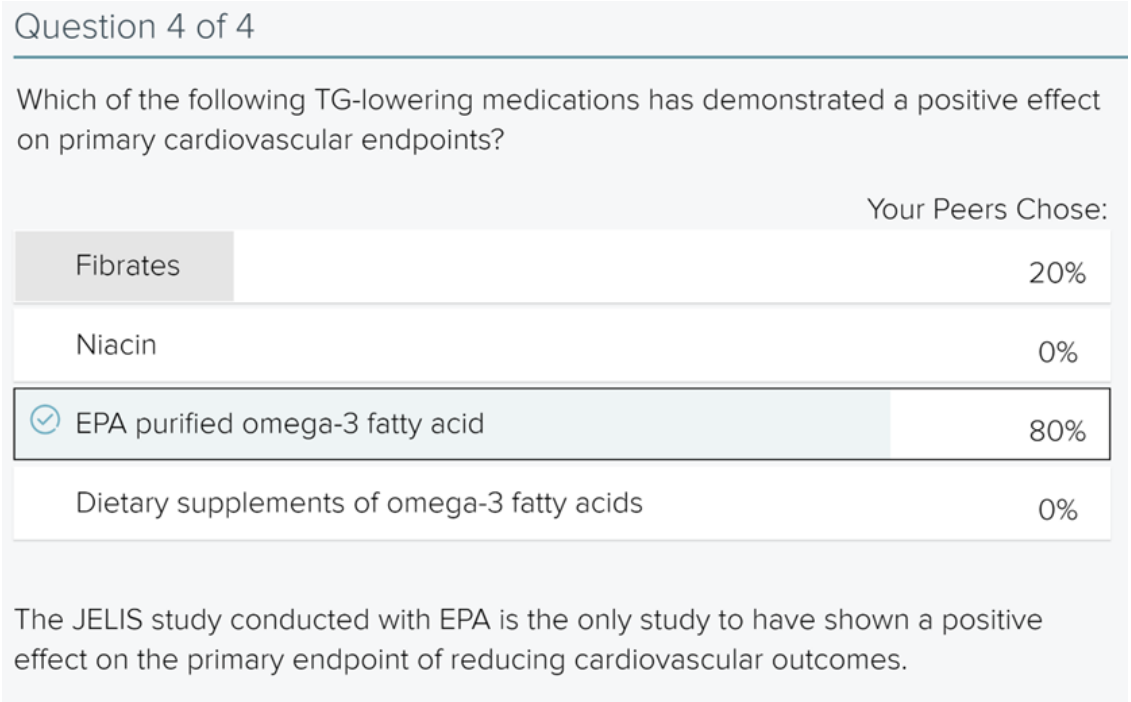
[189] Miller M. What Are the Effects of Statins on Triglycerides and What Are the Results of Major Outcomes Studies? Medscape.org https://www.medscape.org/viewarticle/589010 (Accessed May 13, 2023)

[190] Feingold KR. Triglyceride Lowering Drugs. [Updated 2021 Apr 1]. In: Feingold KR, Anawalt B, Blackman MR, et al., editors. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK425699/

[191] Zimetbaum P, Frishman WH, Kahn S. Effects of gemfibrozil and other fibric acid derivatives on blood lipids and lipoproteins. J Clin Pharmacol. 1991;31:25–37.

[192] Loomba RS, Arora R. Prevention of cardiovascular disease utilizing fibrates--a pooled meta-analysis. Am J Ther. 2010;17:e182–188.

259. This Amarin-funded, Medscape presentation, **Back to Basics of Dyslipidemia: How Can Addition of EPA Reduce CV Risk,** provides the participant readers with NO information regarding the efficacy of fibrates in treating elevated triglyceride levels. In fact, question 4 of 4 is reproduced below:



260. As readily seen, Amarin/Medscape informs this CME's participants that "*EPA purified omega-3 fatty acid*" (Vascepa) demonstrated "*a positive effect on primary cardiovascular endpoints*" within the 'JELIS study'. However, this statement, while trueful on its face, is also misleading. While the EPA omega-3 fatty acid studied in the JELIS study *did* have an effect on the primary endpoint (the authors detected the primary endpoint in 262 (2.8%) patients in the EPA group and in 324 (3.5%) in controls - a 19% relative reduction in major coronary events), **the result was not statistically significant.** In other words, **the finding was just as likely to be due to chance as it was due to the EPA. That important fact is not shared with the participants.**

261. In addition, nowhere in the presentation do the authors, each of them advisors and consultants to Amarin, share with the participants that the JELIS study was a study conducted in Japan and consisted of only Japanese patients. The authors of JELIS recognize this fact and write that one of the limitations of the JELIS study is the strictly Japanese patient load leading them to write, "*Because our population was exclusively Japanese, we cannot generalise*[193] *our results to other populations*."[194]

262. On December 20, 2019, Medscape released, 'From Medscape Education Cardiology', a CME course titled, "**Omega-3s vs Pure EPA in Clinical Practice: What Do CV Outcomes Trials Tell Us**?" by P. Gabriel Steg, MD, Deepak L. Bhatt, MD, MPH, Matthew J. Budoff, MD, and William S. Weintraub, MD.[195] This program was also "[*s]upported by an independent educational grant from Amarin*".[196] This program can also still be accessed in 2023.

263. The stated goal of this activity was,

> "*…to discuss the clinical trial evidence supporting the use of eicosapentaenoic acid (EPA) for cardiovascular (CV) risk reduction, including issues related to cost and strategies to manage patients with elevated triglycerides (TGs)*."[197]

264. The 'attendee' is then given four questions to review before listening to the course speakers and seeing the course PowerPoint slides. Question 3 of 4 in this course asks,

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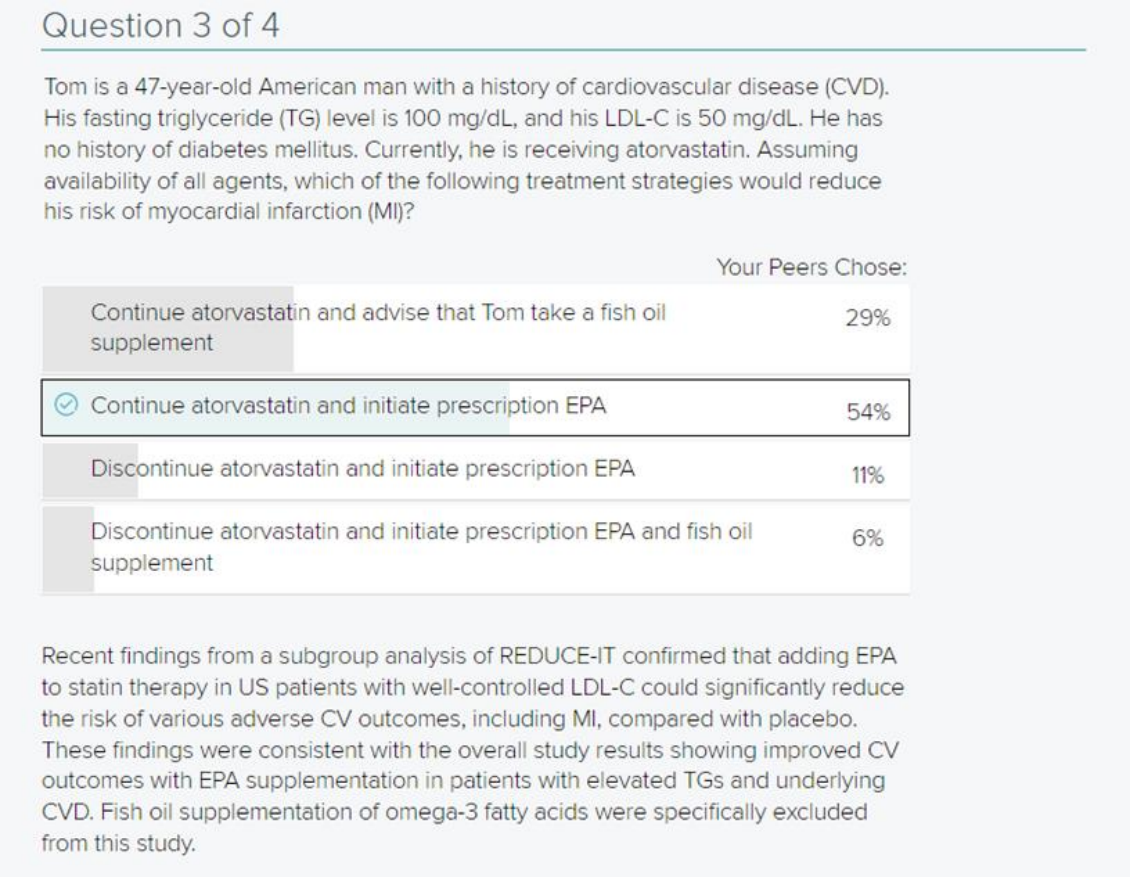
[193] Generalizability of a study's results is referred to as 'external validity', e.g., whether causal relationships can be generalized to different measures, persons, settings, and times. Steckler A, McLeroy KR. The importance of external validity. Am J Public Health. 2008 Jan;98(1):9-10.

[194] Yokoyama M, Origasa H, Matsuzaki M, et al. for the Japan EPA lipid intervention study (JELIS) Investigators. Effects of eicosapentaenoic acid on major coronary events in hypercholesterolaemic patients (JELIS): a randomised open-label, blinded endpoint analysis. The Lancet 2007; March 31, 369:1090-1098.

[195] The three editors of this program were George Boutsalis, PhD, Senior Medical Education Director, **Medscape, LLC**, Zach Hartman, PhD, Scientific Content Manager, **Medscape, LLC**, and Asha P. Gupta, PharmD, RPh Scientific Content Manager, **Medscape, LLC.**

[196] https://www.medscape.org/viewarticle/922880. (Accessed May 13, 2023)

[197] Id.



265. Of importance are the following 'facts' put forth within this Amarin sponsored CME Medscape course:

- 'Tom' has a history of cardiovascular disease.
- 'Tom's fasting triglyceride level is **100 mg/dl**.
- 'Tom' does not have a history of diabetes mellitus.
- 'Tom' is currently taking the statin, atorvastatin although the dosage which he is taking is not shared.

266. The 'correct' answer, as per Medscape, is the green-shaded row with the check mark: "*Continue atorvastatin and initiate prescription EPA*" (the second row) which they report to have been selected by 54% of course participants. It is important to repeat that the only

"*prescription EPA*" drug available then (and now) is Vascepa. [198]

267. It is of critical importance to note that this Amarin/Medscape CME course was released on December 20, 2019, **one day after the FDA approved the label change for Vascepa**. As a result of the label change on December 19, 2019, the 'indication' for Vascepa went from an "*adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia*" to,

- an **adjunct to maximally tolerated statin therapy *and***
  - established cardiovascular disease ***or***
  - diabetes mellitus ***and*** 2 or more additional risk factors for cardiovascular disease.
- an adjunct to diet to reduce TG levels in adult patients with **severe (≥ 500 mg/dL) hypertriglyceridemia**. [199]

268. The reader is informed that 'Tom' is currently taking atorvastatin, **but the dose being taken is not provided**. This suggests the dose is not relevant even though the FDA-approval for Vascepa states that 'Tom' must be on the "**maximally tolerated statin therapy**" to be eligible for Vascepa. Therefore, an EPA such as Vascepa *is not indicated* unless 'Tom' is currently taking the "*maximally tolerated dosage*" of atorvastatin and, therefore, on that basis alone, the 'answer' is incorrect, misleading, and untruthful. Failure to provide this required information by Amarin suggests that the dose of the statin being taken is, in fact, irrelevant and this would increase sales of Vascepa for individuals such as 'Tom' who may not, in fact, be taking the "*maximally tolerated statin therapy*".

269. The reader is also informed that 'Tom's' triglyceride level is **100 mg/dL.**

[198] Icosapent ethyl (Vascepa) is a highly purified and stable EPA ethyl ester.
[199] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202057s035lbl.pdf (Accessed May 13, 2023).

270. Again, reference to the 2019 Vascepa label indicates that it is indicated when adult patients have elevated triglyceride (TG) levels **(≥ 150 mg/dL)** **and** established cardiovascular disease (which the fictional 'Tom' does have). Therefore, despite preexisting cardiovascular disease, 'Tom' does not have the FDA-required level of hypertriglyceridemia for the prescription of Vascepa.

271. By limiting the proffered information to a triglyceride level of 100 mg/dL, Amarin, in its sponsored Medscape CME, is looking to expand the use of Vascepa beyond those indications listed within the FDA-approved product inset (label). And Medscape is all too happy to provide its digital, on-line 'soapbox' to assist Amarin.

272. Below is the embedded question just discussed, now showing the answers given by physicians before (pre-assessment) and after (post-assessment) they took the program.

QUESTION #1: For a patient with metabolic syndrome with elevated low-density lipoprotein (LDL) and triglycerides (TG), which of the following would be an appropriate treatment regimen?

		Cardiologists (n=119; *P* <.05)		Primary Care Physicians (n=217; *P* <.05)	
		Pre-assessment %(n)	Post-assessment %(n)	Pre-assessment %(n)	Post-assessment %(n)
A	Atorvastatin	24% (29)	10% (12)	16% (35)	7% (16)
B	Omega-3 fatty acid dietary supplement	1% (1)	2% (2)	6% (13)	1% (3)
C	Atorvastatin plus omega-3 fatty acid dietary supplement	24% (28)	7% (8)	31% (67)	8% (17)
D	Atorvastatin plus prescription omega-3 fatty acid containing soley EPA	51% (61)	82% (97)	47% (102)	83% (181)

98. The pre-assessment versus post-assessment increase in the number of participants who picked, "*Atorvastatin plus prescription omega-3 fatty acid containing solely EPA*" is striking and reflects the power of improper and misleading statements to change beliefs. Before taking the Amarin-sponsored Medscape program, 51% of the cardiologists selected, "*Atorvastatin plus*

prescription omega-3 fatty acid containing solely EPA" (AKA Vascepa). However, after taking the program, 82% – an increase of 61% - selected that answer. For primary care physicians, the figures went from 47% to 83% – an increase of 77%. This further strong evidence that off-label, untruthful, and/or false presentations would result in increased prescribing of the sponsors' pharmaceutical products leading to the submission of claims to the Government Healthcare Programs, the particulars of which, upon information and belief, are peculiarly within the pharmaceutical companies' knowledge.[200]

273. Three of the four 'lecturers' within this Medscape program, '**Omega-3s vs Pure EPA in Clinical Practice: What Do CV Outcomes Trials Tell Us?**' are also authors of the REDUCE-IT study, discussed below in the question and answer.[201] Therefore, they, and by extension, Amarin, had **actual and constructive knowledge that it would be misleading, false, and untrue to rely upon the limited findings from the REDUCE-IT study to support prescribing an EPA such as Vascepa to an individual such as the fictional 'Tom' in the instant course under discussion.**

274. Regarding the inclusion/eligibility criteria for entry into the REDUCE-IT study, the following language is noted:

[200] The Chorches decision, at 89, held that "…the approach taken by the Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits… have overtly adopted a 'more lenient' pleading standard. Those courts have allowed a complaint that does not allege the details of an actually submitted false claim to pass Rule 9(b) muster by 'alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.' Grubbs, 565 F.3d at 190 (5th Cir. 2009); U.S. ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1172 (10th Cir. 2010) (adopting Grubbs standard); Ebeid ex rel. U.S. v. Lungwitz, 616 F.3d 993, 998-99 (9th Cir. 2010) (same); Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 156-57 (3d Cir. 2014) (same); Heath, 791 F.3d at 126 (D.C. Cir. 2015) (same); cf. Lusby, 570 F.3d at 854 (7th Cir. 2009) ('We don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit.'"

[201] Moderator P. Gabriel Steg, MD and panelists Deepak L. Bhatt, MD, MPH and Matthew J. Budoff, MD.

"*Patients could be enrolled if they…had a* ***fasting triglyceride level of 150 to 499 mg per deciliter****…and had been receiving a stable dose of a statin for at least 4 weeks.*"[202]

275. As such, **Medscape's 'Tom' would not even have qualified for inclusion into the REDUCE-IT study**, the very study Amarin is relying upon for a more expansive use of Vascepa. Tom's **fasting TG level of 100 mg/dL would have disqualified him**. Therefore, it is inappropriate and misleading to use REDUCE-IT as support for the premise that Vascepa would be indicated for 'Tom' within the course sponsored by Amarin and published by Medscape.

276. By recommending "*interventions with EPA alone*" in 2013 when Vascepa was **not approved by the FDA for the treatment of TG levels less than 500 mg/dL**, this statement by Amarin/Medscape, is 'off-label', untruthful, misleading, and false promotion.

(6) BAYER/JANSSEN AND XARELTO

452. Bayer's anticoagulant medication, Xarelto (rivaroxaban), has several indications. However, in **June 2013**, the FDA denied this blockbuster drug as an indication for the prevention of stent thrombosis in acute coronary syndrome (ACS) due to excessive, even catastrophic, bleeding, and insufficient data. Xarelto 10 mg was not approved to reduce the risk of major cardiovascular events in patients with chronic coronary artery disease until **October 11, 2018**.

453. Medscape had actual notice of the June 2013 action by the FDA for, on June 28, 2013, Medscape broadcast '**FDA Refuses Rivaroxaban Stent-Thrombosis Indication for Now**' stating, "*The FDA has given a complete response letter (CRL) to one of the companies behind rivaroxaban (Xarelto, Bayer Pharma/Janssen Pharmaceuticals) indicating that it won't, for now,*

[202] Bhatt DL, Steg PG, Miller M, et al; REDUCE-IT Investigators. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. N Engl J Med. 2019 Jan 3;380(1):11-22 at 12.

approve the oral factor Xa inhibitor for prevention of stent thrombosis in patients with acute coronary syndromes." [203]

454. A few months later, however, in **October 2013**, Medscape started publishing Bayer-funded CME which promoted Xarelto for this very usage. **New Solutions in Secondary Prevention of ACS: The Role of Novel Anticoagulants**, published in October 2013, illustrates this off-label advocacy. [204] In addition to the three physician presenters, Caroline M. Padbury, B. Pharm of Medscape was the 'Lead Scientific Director'.

455. The program has a single embedded multiple-choice question at the beginning, and end, of the program: "*What effect does rivaroxaban have on stent thrombosis?*" This enables Bayer to compare the before versus after measures to determine the impact of the program on cardiologists.

456. The "*Correct Answer*" to the rivaroxaban question is identified as, "*In ATLAS 2—TIMI 51 rivaroxaban 2.5 mg twice daily significantly reduced stent thrombosis and mortality over 2 years*." The Answer Explanation further reinforces the desirability of using Xarelto for stent thrombosis:

> "*In ATLAS 2—TIMI 51, rivaroxaban 2.5 mg twice daily significantly reduced stent thrombosis (1.5% vs 1.9%, P=.023) and mortality (1.35% vs 2.27, P=.014 using modified intention to treat). Use of rivaroxaban 5 mgs twice daily was associated with a nonsignificant reduction in stent thrombosis and no reduction in mortality. In animal models, rivaroxaban plus DAPT significantly reduced thrombosis burden by 98% compared to DAPT alone at 79% (P<.001)*."

457. The directive here is that physicians should use Xarelto to prevent stent thrombosis.

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[203] https://www.medscape.com/viewarticle/807075#:~:text=RARITAN%2C%20New%20Jersey%20%E2%80%94%20The%20FDA,acute%20coronary%20syndromes%20%5B1%5D.

[204] https://www.medscape.org/viewarticle/812061 Published October 9, 2013, accessed May 27; still accessible in 2023.

Most U.S. physicians would probably not realize that this advocated use was off-label because they are poor at identifying off-label uses, even for drugs they themselves have prescribed within the past twelve months.[205]

(7) MYLAN AND MONOAMINE OXIDASE INHIBITORS

460. Another dangerously misleading CME program is **Monoamine Oxidase Inhibitors: Bridging the Gaps in the Treatment of Major Depression**,[206] published February 16, 2013, and still accessible in 2023. This Mylan Specialty, L.P. sponsored program was 'authored' by Joseph F. Goldberg, MD. Victor Otcheretko, MD, Scientific Director, Medscape, LLC and Carol Cadmus, Senior Clinical Editor, Medscape, LLC, were the Editors.

461. This program misleads the reader from the very beginning. Rather than being wholly about using monoamine oxidase inhibitors (MAOs) for Major Depression, as the goal, learning objectives, and title advertise, it consists of two case histories about Major Depression, followed by a case history about Bipolar Depression. In other words, it consists of two cases for which antidepressants are FDA-approved, and one case for which they are not. **Antidepressants, including the older class of antidepressants known as the MAOs, do not have an indication for depression in patients with bipolar disorder**. That is because they can cause a patient with bipolar disorder to switch from depression to mania and worsen the course of the illness.[207] Nevertheless, this CME program consistently touts monoamine oxidase inhibitors as less dangerous than they are. For example, the program claims:

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[205] Chen DT, Wynia MK, Moloney RM, Alexander GC. U.S. physician knowledge of the FDA-approved indications and evidence base for commonly prescribed drugs: results of a national survey. Pharmacoepidemiol Drug Saf. 2009 Nov;18(11):1094-100.

[206] https://www.medscape.org/viewarticle/779552 (Accessed May 13, 2023).

[207] https://www.camh.ca/en/health-info/mental-illness-and-addiction-index/antidepressant-medications (Accessed May 13, 2023).

"*Different classes of antidepressants can induce manic symptoms, with* ***MAOIs and bupropion being more benign than selective serotonin reuptake inhibitors (SSRIs)*** *or tricyclic antidepressants*." (Emphasis Added)

462. The most benign antidepressant is bupropion. Following that are the selective serotonin reuptake inhibitors, such as Prozac and Zoloft, but not Paxil. In the Psychopharmacology Algorithm Project at Harvard Medical School, the algorithm for how to treat bipolar depression does not even mention MAOIs.[208]

463. At the beginning of the program, Medscape announces that it, "*encourages Authors to identify investigational products or off-label uses of products regulated by the US Food and Drug Administration, at first mention and where appropriate in the content*." Dr. Goldberg identifies four such off-label uses for drugs unrelated to Mylan. However, he does not mention that the four MAOIs he is promoting for Bipolar Depression are, in fact, off-label. Dr. Goldberg's advocacy for MAOIs in Bipolar Depression, in the absence of a notice indicating these drugs have not been approved by the FDA, is misleading.

464. Physicians often do not know what uses are off-label, even for commonly prescribed drugs. A national survey presented physicians with a drug name and a condition and found physicians could only accurately guess whether the drug had an indication for that condition 55% of the time.[209] For drugs they themselves reported having prescribed within the past 12 months, the average was 60%.

465. Like most Medscape programs, Dr. Goldberg's presentation may not look biased on the surface. However, comparing what Dr. Goldberg says in this program, sponsored by Mylan,

[208] https://psychopharm.mobi/algo_live/ (Accessed May 13, 2023).
[209] Chen DT, Wynia MK, Moloney RM, Alexander GC. U.S. physician knowledge of the FDA-approved indications and evidence base for commonly prescribed drugs: results of a national survey. Pharmacoepidemiol Drug Saf. 2009 Nov;18(11):1094-100.

to what he said elsewhere on the same topic, is illuminating. In this Medscape program, where the anticonvulsant lamotrigine competes with MAOIs as treatment for bipolar depression, Dr. Goldberg says:

> "*Despite its popular off-label use for the acute treatment of bipolar depression,* ***lamotrigine was found to be no better than placebo on the primary outcome analyses undertaken across 5 randomized, double-blind, placebo-controlled monotherapy trials***." (Emphasis added).

466. In contrast, in 2004, in the Medscape program, '**Rapid-Cycling Bipolar Disorder: Emerging Treatments and Enduring Controversies**'[210,211] along with his co-author, Jinger Hoop, MD, in a program sponsored by AstraZeneca, Drs. Goldberg and Hoop wrote, "Lamotrigine has demonstrated effectiveness for acute bipolar depression."

467. In another place, embedded material claims that, *"[t]ricyclic antidepressants added to a mood stabilizer carry a higher risk for inducing manic or hypomanic symptoms than MAOIs*." In fact, compared with tricyclic antidepressants, just about any antidepressant will look safer.

468. The conclusion that "*MAOIs are broad-spectrum antidepressants that are largely underutilized and underappreciated, particularly in patients with… bipolar depression (when combined with a mood stabilizer)*," is an off-label promotion which is not only misleading but also potentially dangerous.

469. WebMD itself, published on-line '**Monamine Oxidase Inhibitors (MAOI)s**'[212], which was not apparently sponsored by a pharmaceutical company. It was "*written by WebMD Editorial Contributors*" and "*Medically Reviewed by Jennifer Casarella, MD on August 28, 2022.*"

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[210] https://www.medscape.org/viewarticle/495236 (Accessed August 18, 2023).
[211] No Medscape editor or CMR reviewer is listed.
[212] https://www.webmd.com/bipolar-disorder/monoamine-oxidase-inhibitors#:~:text=In%20addition%2C%20some%20experts%20think,Drug%20interactions. (Accessed August 18, 2023).

470. Therein, the WebMD program states,

> "…*some experts think that MAOIs may be especially likely to cause mood switches from depression to mania in people with bipolar disorder, and therefore, mood changes must be monitored closely*."[213,214,215,216,217]

471. In fact, Dr. Goldberg, himself, in 2003, when writing in a peer-reviewed medical journal article, without sponsorship, wrote, "*About one-quarter to one-third of bipolar patients may be inherently susceptible to antidepressant-induced manias*,"[218] a fact he omitted from Mylan's sponsored Medscape program in 2013. Medscape's 2013 program is still accessible in 2023, unedited and devoid of changes consistent with this new information available within PubMed and on Medscape's parent company's own website.

(C) CONTRIBUTION TO AND EXACERBATION OF THE OPIOID EPIDEMIC

472. In 2013, the U.S. Department of Health and Human Services declared the misuse of prescription opioids an "epidemic"[219], while the New York Times described it as the "*deadliest drug crisis in American history*"[220], a crisis which has its roots in the overprescription of opioid painkillers.[221] Adapting a methodology used by the CDC to estimate the cost of the opioid epidemic

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[213] Id.
[214] Taylor DM, Cornelius V, Smith L, Young AH. Comparative efficacy and acceptability of drug treatments for bipolar depression: a multiple-treatments meta-analysis. Acta Psychiatr Scand. 2014 Dec;130(6):452-69.
[215] Boerlin HL, Gitlin MJ, Zoellner LA, Hammen CL. Bipolar depression and antidepressant-induced mania: a naturalistic study. J Clin Psychiatry. 1998 Jul;59(7):374-9.
[216] Ali S, Milev R. Switch to mania upon discontinuation of antidepressants in patients with mood disorders: a review of the literature. Can J Psychiatry. 2003 May;48(4):258-64.
[217] Zarate CA Jr, Tohen M, Baraibar G, Kando JC, Mirin J. Prescribing trends of antidepressants in bipolar depression. J Clin Psychiatry. 1995 Jun;56(6):260-4.
[218] Goldberg JF, Truman CJ. Antidepressant-induced mania: an overview of current controversies. Bipolar Disord. 2003 Dec;5(6):407-20.
[219] Salmond S, Allread V. A Population Health Approach to America's Opioid Epidemic. Orthop Nurs. 2019 Mar/Apr;38(2):95-108.
[220] Katz J. (2017, August 10). Short answers to hard questions about the opioid crisis. The New York Times. https://www.nytimes.com/interactive/2017/08/03/upshot/opioid-drug-overdose-epidemic.html. (Accessed May 9, 2023).
[221] Id.

in 2017, the U.S. Congress Joint Economic Committee (JEC) estimates the opioid epidemic cost $1.04 trillion in 2018, $985 billion in 2019 and nearly cost the U.S. nearly $1.5 trillion in 2020 alone.[222]

473. One-third of Medicare beneficiaries received an opioid prescription in 2017.[223] Literature to date has focused on supply-side factors influencing opioid prescribing - for example, the role of physician preferences, "pill mills," or **promotional activities by pharmaceutical companies**.[224]

474. By 2017, 38% of non-elderly adults diagnosed with an opioid use disorder (OUD) were covered by Medicaid, reflecting the central role of this public insurance program in addressing the crisis.[225,226] Medicaid has become the largest source of financing for OUD treatment and provides coverage for medication for opioid use disorder (MOUD), the first-line standard of care, in addition to other pertinent behavioral health therapies.[227,228,229,230]

475. Among the roughly 30% (6.1 million of 20.3 million) of veterans who use VA services, the prevalence of overdose deaths from non-synthetic opioids roughly doubled between

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[222] U.S. Congress Joint Economic Committee. JEC Analysis Finds Opioid Epidemic Cost U.S. Nearly $1.5 Trillion in 2020. https://beyer.house.gov/news/documentsingle.aspx?DocumentID=5684#:~:text=In%20addition%20to%20the%20toll,nearly%20%241.5%20trillion%20in%202020. (Accessed May 3, 2023).

[223] Sabety AH, Sherry TB, Maestas N. Opioid use in older adults and Medicare Part D. Health Serv Res. 2021 Apr;56(2):289-298.

[224] Id.

[225] Peterson L, Murugesan M, Nocon R, et al. Health care use and spending for Medicaid patients diagnosed with opioid use disorder receiving primary care in Federally Qualified Health Centers and other primary care settings. PLoS One. 2022 Oct 18;17(10):e0276066.

[226] Orgera K, Tolbert J. The Opioid Epidemic and Medicaid's Role in Facilitating Access to Treatment. Kaiser Family Foundation; 2019.

[227] Id.

[228] Substance Abuse and Mental Health Services Administration. Medication-Assisted Treatment (MAT) 2021. Available from: https://www.samhsa.gov/medication-assisted-treatment. (Accessed August 13, 2023).

[229] The Medicaid Outcomes Distributed Research Network. Use of Medications for Treatment of Opioid Use Disorder Among US Medicaid Enrollees in 11 States, 2014–2018. JAMA. 2021;326(2):154–64.

[230] McCarty D, Gu Y, McIlveen JW, Lind BK. Medicaid expansion and treatment for opioid use disorders in Oregon: an interrupted time-series analysis. Addiction science & clinical practice. 2019;14(1):31.

2001 and 2009,[231] and overdose deaths in this population have continued to rise dramatically, showing a 65 percent increase from 2010 to 2016 alone.[232]

476. TRICARE is the insurance plan of the US Department of Defense and provides health care coverage for over 9 million beneficiaries.[233] Approximately 20% of the covered population is active-duty military, with the remainder composed of retirees, disabled personnel, and dependents.[234] Despite decreasing fill rates in recent years, nearly 1 in 4 active duty and retired service members had a filled opioid prescription in 2017.[235] Active duty and activated Guard/Reserve members who received an opioid prescription had a median of 2 fills per patient in 2017, while retirees had a median of 7 fills per patient. Moreover, a higher percentage of retirees' opioid prescriptions were for high-dose prescriptions compared to active duty and activated Guard/Reserve.[236]

477. According to data provided by the Office of Workers' Compensation Programs, spent almost $256 million in financial year 2016.[237]

478. In 2006, Endo Pharmaceuticals introduced both a generic extended-release oxycodone pill to compete with OxyContin and another opioid, an oxymorphone pill called

[231] Bohnert ASB, Ilgen MA, Trafton JA, et al.. Trends and regional variation in opioid overdose mortality among veterans health administration patients, fiscal year 2001 to 2009. Clin J Pain. 2014;30(7):605–612.
[232] Lin LA, Peltzman T, McCarthy JF, et al.. Changing trends in opioid overdose deaths and prescription opioid receipt among veterans. Am J Prev Med. 2019;57(1):106–110.
[233] Schoenfeld AJ, Jiang W, Harris MB, Cooper Z, Koehlmoos T, Learn PA, Weissman JS, Haider AH. Association Between Race and Postoperative Outcomes in a Universally Insured Population Versus Patients in the State of California. Ann Surg. 2017 Aug;266(2):267-273.
[234] Id.
[235] Surveillance Snapshot: Trends in Opioid Prescription Fills Among U.S. Military Service Members During Fiscal Years 2007–2017. https://health.mil/News/Articles/2019/10/01/Trends-in-Opioid-Prescription-Fills?type=Articles. (Accessed August 13, 2023).
[236] Id.
[237] Report to the Office of Workers' Compensation Programs. OWCP Did Not Ensure Best Prices and Allowed Inappropriate, Potentially Lethal Prescriptions in The FECA Program. https://www.oig.dol.gov/public/reports/oa/2023/03-23-001-04-431.pdf. (Accessed August 13, 2023).

'Opana'.[238] By 2010, the company's extended-release version of Opana was generating more than $1 billion in annual revenue, according to court records. Relator Elizabeth Saenger, PhD discovered that Bill McCarberg, MD, a member of the Speaker's Bureau for Endo Pharmaceuticals, Janssen Pharmaceutica, and Purdue, along with being on the Board of Directors of the now defunct American Pain Society, presented Medscape's '**Opioid Analgesia: Practical Treatment of the Patient with Chronic Pain**, *"[s]upported by an unrestricted educational grant from Endo Pharmaceuticals*" and still available to be accessed in 2023.[239]

479. Dr. McCarberg starts his presentation on Medscape by announcing that he is family practitioner and that he had started the first pain management program with a large managed care organization in Southern California and that he would talk about the treatment of chronic pain. Dr. McCarberg states,

> "*Over the last 10 years, **there has been an emphasis on using more medication in managing chronic pain, and certainly the hallmark of medication management has been the use of opioids***."[240] (Emphasis Added).

Furthermore,

> "*Today, we know that sometimes intervening in a **more aggressive manner** leads to **less chronic pain***." (Emphasis added).

And,

> "*So, **we are tending to get more aggressive early on**, even though treating the continuum of pain is still generally recommended*." (Emphasis added).

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[238] Inside the Opioid Industry's Marketing Machine. Washington Post. December 6, 2019. https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/ (Accessed May 13, 2023).
[239] https://www.medscape.org/viewarticle/469428. (Accessed May 13, 2023).
[240] Id.

And,

"***Chronic pain can be a diagnosis***. *Remember, it is not always possible to achieve a primary diagnosis,* ***yet you need to treat the underlying factors***. *As I showed before, treat the comorbidities; decrease the pain.* ***Even if you cannot achieve a primary diagnosis, that is still okay****, because we want to increase the patient's ability to function and his quality of life*. (Emphasis Added)

480. However, it is necessary to recall that Dr. McCarberg, at the time of his Medscape presentation, admitted that he was, *inter alia*, on the speaker's bureau for Endo Pharmaceuticals.[237] Endo Pharmaceuticals which, according to court documents obtained during the opioid litigation, stated in 2008 regarding its opioid Opana,

"*Most healthcare providers who treat patients with pain agree that* ***patients treated with prolonged opioid medicines usually do not become addicted***. *Physical dependence, which is different from addiction, may develop when taking opioids for pain relief for a long time.*

"This means that your body adapts to the drug and you will have withdrawal symptoms if the medicine is stopped or decreased suddenly. ***Taking opioids for pain relief is NOT addiction***."[241] (Emphasis Added)

481. On June 8, 2017, the FDA

"*…requested that Endo Pharmaceuticals remove its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the market. After careful consideration, the agency is seeking removal based on its concern that the*

[241] Case: l:17-md-02804-DAP Doc #: 2251-51 Filed: 08/13/19 1 of 10. PagelD #: 351298. Exhibit 51. Taking a Long-Acting OpioId. https://www.industrydocuments.ucsf.edu/pdf. (Accessed March 28, 2023). It should be noted that the Washington Post reported on December 6, 2019 it in its article, '**The Opioid Files – Inside the opioid industry's marketing machine**' that "*In the Ohio case, the newly unsealed documents delve deep into the marketing strategies of the manufacturers. In 2012, Endo Pharmaceuticals stated on its website for its opioid Opana, a formulation of morphine, that "most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," according to the court documents."*https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/?itid=lk_inline_manual_3.

> *benefits of the drug may no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse*."[242,243]

482. Also in 2006, Medscape offered its digital soapbox to the opioid manufacturer, Cephalon through its Medscape Neurology program. The program, '**Breakthrough Pain: Strategies for Effective Assessment and the Role of Rapid-Onset Opioids in Treatment'**,[244] was sponsored by "*an independent educational grant from Cephalon*"[245] which manufactured and sold two branded fentanyl-based opioids under the names 'Actiq' and 'Fentora'. This CME program used an early form of embedded material, which Relator Elizabeth Saenger, PhD has saved. This program is still available online, unedited, for any interested party to access.

483. In this Medscape program, author Scott M. Fishman, MD and 'Medical Writer, Paula Moyer, MA, wrote,

> "*BTP* (break through pain) *is best managed by adding a* ***rapid-onset medication*** *when the pain occurs. However, some opioids have an onset of action that is too long and consequently does not match the rapid onset of a typical BTP episode. This results in a 'pain gap'…*"[246]

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[242] FDA requests removal of Opana ER for risks related to abuse. https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse. (Accessed May 13, 2023).

[243] After deciding to withdraw its reformulated Opana ER, Endo explored bringing another oxymorphone ER drug to the market or partnering with a third-party generic company as a way to replace its Opana ER revenues. Ultimately, Endo reached an agreement in August 2017 with Impax, the only other authorized seller of an oxymorphone ER product. On January 25, 2021, the FTC is sued Endo Pharmaceuticals Inc., Endo International plc, Impax Laboratories, LLC, and Impax's owner, Amneal Pharmaceuticals, Inc., alleging that the 2017 agreement between Endo and Impax violated the antitrust laws by eliminating competition in the market for oxymorphone ER.

[244] https://www.medscape.org/viewarticle/545163. (Accessed May 12, 2023).

[245] Cephalon Inc. is the predecessor company to Teva Pharmaceuticals, USA, Inc. In 2008, Cephalon settled federal criminal charges and state civil charges for illegally marketing Actiq, a potent rapid-release form of fentanyl, which was administered via a raspberry-flavored fentanyl lollipop. Unredacted Complaint Reveals Fentanyl Manufacturer Teva/Cephalon's Illegal Marketing Strategies. Commonwealth of Virginia Office of the Attorney General. February 10, 2020. https://www.oag.state.va.us/consumer-protection/index.php/news/374-february-10-2020-unredacted-complaint-reveals-fentanyl-manufacturer-teva-cephalon-s-illegal-marketing-strategies. Cephalon aggressively targeted non-cancer prescribers and doctors with sales and promotional visits, including doctors specializing in "*primary care, family medicine, physical medicine, and neurology*," **even though the drugs were only FDA approved to treat cancer patients**. (Id.)

[246] https://www.medscape.org/viewarticle/545163_7. (Accessed May 7, 2023).

370. Although there was, at the time of this presentation and to the present day, no disclosure listed about Dr. Fishman, Dr. Fishman was, in fact, a past board member for the American Pain Society[247,248] and, in 2006, was President of the American Academy of Pain Medicine.

371. On October 5, 2011, Dr. Fishman disclosed in the Journal of the American Medical Association[249] that he acknowledged receiving fees for teaching medical education courses, some of which were funded by drug-company grants, which he had previously failed to disclose. Although there is no disclosure noted by Dr. Fishman in the Medscape presentation, Dr. Fishman has previously disclosed, in 2007, that he is a consultant to Cephalon (and other opioid manufacturers).[250,251] Once again, this is in direct violation of the ACCME standards and the FDA's Guidance document.

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[247] The American Pain Society led the campaign to **promote the concept of "pain as the fifth vital sign"**, which resulted in hospitals across the US introducing smiley-face pain scales into consulting rooms in the 2000s and requiring doctors to prioritize pain treatment. (https://www.theguardian.com/us-news/2019/may/25/american-pain-society-doctors-painkillers#:~:text=The%20American%20Pain%20Society%20led,doctors%20to%20prioritize%20pain%20treatment.) However, in 2016, in light of research documenting the dramatic rise of opioid addiction and opioid-related deaths, delegates at the 2016 American Medical Association meeting voted to stop treating pain as the fifth vital sign because they believe it is likely that the initiative, along with other factors, have exacerbated the opioid crisis.

[248] Between 2012 and 2017, the American Pain Society received $962,724.52 from five opioid manufacturers. (https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf.) (Accessed May 12, 2023).

[249] Fishman SM. Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion. *JAMA.* 2011;306(13):1445.

[250] https://www.documentcloud.org/documents/279187-responsible-opioid-prescribing-info#document/p7/a41600. (Accessed May 12, 2023).

[251] This is not the only instance where authors/presenters in Medscape's CME programs failed to disclose their financial conflicts of interest. On April 3, 2011, John Fauber, a reporter with the **Milwaukee Journal Sentinel/MedPage Today** reported in an article titled '**Academics Profit By Making the Case for Opioid Painkillers**', regarding Aaron Gilson, PhD, a University of Wisconsin "*Pain Group official*", that "***The Journal Sentinel/Medpage Today*** *investigation found* ***five Medscape articles by Gilson about opioids and pain in which the disclosure section states that Gilson "has disclosed no relevant financial relationships***." In an email response, Dr. Gilson wrote, "*Authors don't control how any journal or website chooses to present information in their publication.*" *Katherine Hahn, a spokesperson for WebMD, the parent of Medscape, said Gilson disclosed that he received personal income from drug companies in other articles he wrote for Medscape.* ***She said she is not sure why it was not disclosed in the five articles***." (Emphasis Added). (https://www.medpagetoday.com/special-reports/specialreports/25683). (Accessed May 12, 2023).

372. Nowhere within this Cephalon/Medscape presentation does Dr. Fishman specifically state that the use of oral transmucosal fentanyl citrate (Actiq) was approved "***ONLY***" for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. [252] (Emphasis in the original).

> In addition, please note that this product has been approved **ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.
>
> As such, please note that promotional statements or representations by you that this product may indeed be safe and efficacious in the treatment of diseases or patient populations beyond that contained in your approved labeling may be considered a violation of the Act. If you

(FDA Approval letter for Actiq, November 4, 1999)

374. Cephalon made 'Actiq' a blockbuster by defying the FDA's restrictions to sell 'Actiq' to non-cancer patients.[253] It did so in three main ways:

- by wooing physicians prescribing off-label;
- through sales visits to physicians who were prescribing off-label; and
- by providing physicians and patients with misleading information on 'Actiq's' risks and benefits, often through channels that circumvented FDA scrutiny.[254]

375. The third leg of Cephalon's sales practices was to disseminate misleading messaging about 'Actiq's' risks and benefits, especially through its speaking programs. Cephalon had its speakers promote misconceptions about opioid tolerance, and patients' need for increases

[252] Commonwealth of Virginia, Ex Rel. Mark R. Herring v Teva Pharmaceuticals. Case no. 19-5566-5. Nov. 7, 2019. https://files.constantcontact.com/bfcd0cef001/4d40d0ee-d26b-4727-8109-66e28ca993c4.pdf. (Accessed May 12, 2023).
[253] Id. at 14.
[254] Id.

or escalation in opioid doses to maintain the same pain-relieving or analgesic effect.[255] Cephalon speakers stated that "*tolerance to analgesia is seldom a clinical problem*."[256]

376. In 2004, two years before Dr. Fishman's Cephalon/Medscape presentation, the FDA stated that,

> "***The off-label use of the product*** ('Actiq') ***is staggering . . . the Agency is very concerned that the situation that occurred with Oxycontin may happen again***."[257]

377. The FDA informed Cephalon that off-label prescribing disregards 'Actiq's' serious risks and was "*illegal and, especially with a drug with a risk profile like 'Actiq', raises significant public health concerns*."[258] However, once again, Medscape/WebMD's actions in this regard went unpunished **and this program is still accessible to this day**.

378. Cephalon continued using its so-called 'medical education programs' to promote wrongful off-label use of Actiq.[259] In a 2005 email[260], one of Cephalon's regional sales managers emphasized the importance of using medical education programs to promote sales:

> "*It has been shown time and time again the value that* ***these*** **[CME]** ***programs*** *will bring to your business when conducted in the right way with the right customers…****This is one of the most valuable resources we have to promote our products*** *and I will strongly consider your team's effective utilization of this resource during each of your 2005 annual reviews*." (Emphasis Added)

379. Cephalon's promotion of 'Actiq' from 2001 to 2006 to patients who did not have metastatic cancers grossly disregarded 'Actiq's' known risks and benefits. Millions of 'Actiq'

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[255] Id. at 24.
[256] Id. at 29.
[257] Commonwealth of Virginia, Ex Rel. Mark R. Herring v Teva Pharmaceuticals. Case no. 19-5566-5. Nov. 7, 2019. https://files.constantcontact.com/bfcd0cef001/4d40d0ee-d26b-4727-8109-66e28ca993c4.pdf. at 27. (Accessed May 12, 2023).
[258] Id. at 28.
[259] Id. at 29.
[260] Id.

lozenges went to patients for whom Cephalon and Anesta had not clinically evaluated 'Actiq's' safety, risks, and benefits. More than half a million patients across America bore these risks, taking 'Actiq' for conditions that had not been studied or for which the long-term risks were unknown. And Medscape provided a very large soapbox for Cephalon to stand upon and promote 'Actiq'.

380. In a December 3, 2018, complaint by the City of Salem versus Purdue Pharma L.P. d/b/a Purdue Pharma (Delaware) Limited Partnership et al. (including Cephalon, Inc.) the attorneys for the Plaintiff City of Salem included, under the heading of '**Falsehood That Scientific Evidence Supports the Long-Term Use of Opioids to Improve Patients' Function and Quality of Life**',

> "*Cephalon sponsored a CME written by KOL **Dr. Lynn Webster**, titled **Optimizing Opioid Treatment for Breakthrough Pain**, which was **offered online by Medscape**, LLC from September 28, 2007, through December 15, 2008. The CME taught that Cephalon's Actiq and Fentora "…improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids.*"[261] (Emphasis added).

381. Furthermore, the City of Salem complaint documented that the Defendant Cephalon "*suggested that high dose opioid therapy was safe*" stating,

> *"The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations.*"[262]

[261] City of Salem versus Purdue Pharma L.P. d/b/a Purdue Pharma (Delaware) Limited Partnership et al., December 3, 2018, at 107. https://www.salemma.gov/sites/g/files/vyhlif7986/f/news/complaint_-_salem_v._purdue_et_al._date_stamped_12.3.18_a0530289xb0ba5.pdf. (Accessed May 12, 2023).
[262] Id. at 108.

382. In 2008, Cephalon was fined $425,000,000 for the off-label promotion of, *inter alia*, Actiq.[263] Despite offering Cephalon its on-line soapbox through which it could promote the *"[f]alsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life*", Medscape was not named as a defendant in this action.

383. In 2013, Medscape provided its digital megaphone to Joe Lex, MD, who presented '**New Drugs and Devices From 2011 – 2012 That Might Change Your Practice**'[264], which is still available to be accessed and read in 2023. Therein, he discussed, *inter alia*, "*…10 medicines that we probably should know*…" including the fentanyl sublingual spray, Subsys, manufactured by Insys Therapeutics. In this Medscape presentation, Dr. Lex promotes fentanyl, writing:

> "*Fentanyl is currently considered* ***one of the safest opioids on the market****, and the* ***least physically harmful to the body, especially with long-term or life-term use***."[265] (Emphasis Added).

384. Fentanyl was first developed in 1959 and introduced in the 1960s as an intravenous anesthetic. It is legally manufactured and distributed in the United States. However, **fentanyl is the most potent narcotic on the market for human use. It is approximately 100 times more potent than morphine and 50 times more potent than heroin as an analgesic**.[266] The rate of overdose deaths involving synthetic opioids was more than 18 times higher in 2020 than in 2013.[267] Drug deaths nationwide hit a new record in 2022. 109,680 people died as the fentanyl crisis

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[263] Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing. https://www.justice.gov/sites/default/files/civil/legacy/2014/01/09/Cephalon%20Press%20Release.pdf. (Accessed May 10, 2023).

[264] Lex J. New Drugs and Devices From 2011 – 2012 That Might Change Your Practice. https://www.medscape.com/viewarticle/818206. (Accessed May 12, 2023).

[265] https://www.medscape.org/viewarticle/876762. (Accessed May 11, 2023).

[266] United States Drug Enforcement Administration. Fentanyl. https://www.dea.gov/factsheets/fentanyl#:~:text=Fentanyl%20is%20a%20potent%20synthetic,than%20heroin%20as%20an%20analgesic. (Accessed May 12, 2023).

[267] Centers for Disease Control and Prevention. Synthetic Opioid Overdose Data. June 6, 2022. https://www.cdc.gov/drugoverdose/deaths/synthetic/index.html. (Accessed May 12, 2023).

continued to deepen, according to preliminary data released by the Centers for Disease Control and Prevention.[268]

385. In 2017, in those states where the drug crisis was particularly severe, fentanyl was involved in over half of all overdose fatalities.[269] Yet, in 2013, Medscape were promoting fentanyl as "…*one of the safest opioids on the market, and the least physically harmful to the body, especially with long-term or life-term use*."[270]

386. In 2022, provisional data indicated that more than two thirds (68%) of the reported 107,081 drug overdose deaths in the United States involved, principally, illicitly manufactured fentanyls.[271] But Medscape continues to allow this program to be accessed and read, although not for CME credit.

387. On March 29, 2016, John Maeglin, now Director, Grant Specialist at Medscape, wrote an email to Daniel Brennan, then Chief Operating Officer of Insys Therapeutics, Inc. In the email, reproduced below, Mr. Maeglin shares with Mr. Brennan a link to "*an example of a good, relevant medical education* ***developed by Medscape*** *that is sent/available to* ***thousands of targeted physicians and nurses***."[272,273] (Emphasis added).

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[268] Kariisa M, O'Donnell J, Kumar S, Mattson CL, Goldberger BA. Illicitly Manufactured Fentanyl-Involved Overdose Deaths with Detected Xylazine - United States, January 2019-June 2022. MMWR Morb Mortal Wkly Rep. 2023 Jun 30;72(26):721-727.

[269] Housman P. To the Point: The Fentanyl Crisis, Why Now, Why So Deadly? American university. Washington, D.C. https://www.american.edu/cas/news/to-the-point-the-fentanyl-crisis.cfm#:~:text=It's%20the%20deadliest%20drug%20crisis,around%20200%20Americans%20every%20day. (Accessed May 11, 2023).

[270] https://www.medscape.org/viewarticle/876762. (Accessed May 11, 2023).

[271] Kariisa M, O'Donnell J, Kumar S, Mattson CL, Goldberger BA. Illicitly Manufactured Fentanyl–Involved Overdose Deaths with Detected Xylazine — United States, January 2019–June 2022. MMWR Morb Mortal Wkly Rep 2023;72:721–727. DOI: http://dx.doi.org/10.15585/mmwr.mm7226a4 (Accessed September 14, 2023).

[272] Dan Brennan. FW: Medscape: Medical Cannabis: Pharmacy Focus on .... 2016 March 30. Insys Litigation Documents. Unknown. https://www.industrydocuments.ucsf.edu/docs/gpxm0264. (Accessed May 13, 2023).

[273] A glossy, Insys-funded CME brochure from Medscape is available at www.medscape.org/interview/cancer-pain. (Accessed May 13, 2023).

388. As can be seen within the email thread, Mr. Brennan sends the email to various principles within Insys Therapeutics, including John Kapoor.[274] Therein, Mr. Brennan shares,

> "*John Maeglin is* ***a representative of Medscape*** *and he approached me with a medical education idea of* ***having them develop a piece about the use of and their role in Breakthrough Cancer Pain and whether or not this adds or subtracts to the current ''Opioid Epidemic''*** *- written from the physician experts point of view*."[275]

[274] In October 2017, Kapoor was arrested in Arizona and charged with RICO conspiracy, conspiracy to commit wire fraud, and conspiracy to violate the Anti-Kickback Law. ('Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering'. www.justice.gov. 26 October 2017.) In January 2020, a "…*federal judge sentenced John Kapoor, the founder of the opioid manufacturer Insys Therapeutics, to five and a half years in prison Thursday for his role in a racketeering scheme that bribed doctors to prescribe a highly addictive opioid and misled insurers*." https://www.nytimes.com/2020/01/23/health/opioids-insys-kapoor-prison.html. (Accessed May 11, 2023).

[275] Id.

Email Message

From: Dan Brennan [dbrennan@insysrx.com]
Sent: Wednesday, March 30, 2016 12:39 AM
To: Nellie Oquendo; John Kapoor; Raimonds Dzelme; Lew Fredane; Santosh Vetticaden
Subject: FW: Medscape: Medical Cannabis: Pharmacy Focus on ...

All, please see the link below as an example of a good, relevant medical education piece developed by Medscape that is sent/available to thousands of targeted physicians and nurses. This particular piece is on Medical Cannabis, and makes mention of THC and CBD and the current, increased use and benefit of medical cannibas for numerous medical conditions.

John Maeglin is a representative of Medscape and he approached me with a medical education idea of having them develop a piece about the use of [redacted] and their role in Breakthrough Cancer Pain and whether or not this adds or subtracts to the current "Opioid Epidemic" – written from the physician experts point of view.

He and the Medscape team would like to visit Insys to share/explain their Medscape platform and describe their medical education idea on [redacted]TCP more in depth. Nellie, is there a date in mid-April that looks good for John's calendar that we can work around? (And Nellie, feel free to follow the link below to the Medical Cannabis article and sign up John/yourself for the free subscription – I think you will both find the article and the entire Medscape offering relevant/valuable). Thx.
Dan

From: Maeglin, John [mailto:jmaeglin@medscape.net]
Sent: Tuesday, March 29, 2016 12:31 PM
To: Dan Brennan <dbrennan@insysrx.com>
Subject: Medscape: Medical Cannabis: Pharmacy Focus on ...

Hey, Dan, it was great to see you last Friday. I thought the piece below might be of interest.

In follow up to our conversation, when do you think we might be able to meet with your team in AZ to discuss professional medical education's role in the appropriate use of breakthrough pain? Once we set a date, my team would set up an advance teleconference with you to discuss the meeting agenda to ensure that your team gets the most out of the meeting.

Thank you.

John Maeglin
Senior Director, Medical Education
Medscape Education
C) [redacted]
jmaeglin@medscape.net
www.medscape.org/vision

389. As admitted to by 'WebMD/Medscape' itself in a June 22, 2016, email from Dr. Zatz, then President of WebMD, to John Kapoor, then the former CEO of Insys Therapeutics, Inc.,

> "*The most effective campaigns combine rep visits with* ***the power of digital information and promotion****, and we* (WebMD/Medscape) *are by far* ***the best platform when it comes to supporting brands' need for reach and engagement with target list physicians***."[276] (Emphasis Added).

390. Of particular interest is Dr. Zatz' statement,

> "*Lastly, we should continue to look for ways we can take advantage of our* ***unique reach*** *to patients and care givers who are* ***increasingly dictating to their physicians what they expect from their treatment***." (Emphasis Added).

399. In other words, Medscape is informing Insys Therapeutics, Inc., that it could promote their products, including Subsys. This scheme defrauded Medicare, Medicaid, the Veterans Administration, and other agencies and the size of the fraud is enormous.

400. On or about June 5, 2019, Insys Therapeutics, manufacturer of the opioid, Subsys, agreed to a global resolution to settle the Department of Justice's separate criminal and civil investigations. As part of the civil resolution, Insys agreed to pay $195 million to settle allegations that it violated the False Claims Act. Both the criminal and civil investigations stemmed from Insys' payment of kickbacks and **other unlawful marketing practices in connection with the marketing of Subsys**.

401. Neither WebMD nor Medscape was named in this violation of the False Claims Act despite their role in the promotion of Subsys as described in detail *infra*. In fact, Medscape aided,

[276] Zatz, Steven. WebMD/Medscape follow-up. 2016 June 22. Insys Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/ntdn0264. (Accessed May 11, 2023).

abetted, colluded, and conspired not only with Insys Therapeutics but with several pharmaceutical manufacturers, including, but not limited to, Bristol-Myers Squibb (BMS), and Collegium, and to promote their drugs even just before (when negotiations were obviously underway), or just after, the companies signed 'corporate integrity agreements' promising to not promote their drugs off-label.

402. The epidemic of opioid abuse and addiction has its origins in the pharmaceutical industry and the medical community.[277] The combination of **aggressive marketing of prescription opioids by manufacturers, promotion by marquee professors**, and endorsement by pain societies contributed to a cultural transformation.[278] Over the past three decades prescription opioids have been increasingly used long-term to **manage chronic, non-cancer pain even though they are not approved for this use**.[279,280,281,282] From 1999 to 2019, nearly 247,000 people died in the US from overdoses involving prescription opioids, a quadrupling of the rate within that time period. [283] Between 2019 and 2020 alone, deaths from prescription opioids increased 21.2%.[284]

[277] Psaty BM, Merrill JO. Addressing the Opioid Epidemic - Opportunities in the Postmarketing Setting. N Engl J Med. 2017 Apr 20;376(16):1502-1504.
[278] Id.
[279] Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997–2002. Journal of Pain & Symptom Management. 28(2):176–88.
[280] Gureje O, Von Korff M, Simon GE, Gater R. Persistent pain and well-being: a World Health Organization Study in Primary Care. JAMA. 1998 Jul 8;280(2):147-51.
[281] Sullivan MD, Edlund MJ, Fan MY, DeVries A, Braden JB, Martin BC. Trends in use of opioids for non-cancer pain conditions 2000-2005 in commercial and Medicaid insurance plans: the TROUP study. Pain. 2008 Aug 31;138(2):440-449.
[282] Zacny J, Bigelow G, Compton P, Foley K, Iguchi M, Sannerud C. College on Problems of Drug Dependence taskforce on prescription opioid non-medical use and abuse: position statement. Drug Alcohol Depend. 2003 Apr 1;69(3):215-32.
[283] https://www.fairfieldct.org/Opioids (Accessed May 11, 2023).
[284] SHADAC analysis of CDC 2020 Provisional Drug Overdose Death Counts. https://www.shadac.org/opioid-epidemic-united-states. (Accessed May 11, 2023).

403. Data shows that most people who misuse opioids begin with opioids obtained from a legitimate prescription. As reported by the Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse Pain in 2017, "*Although heroin and illicitly manufactured fentanyl account for an increasing proportion of opioid-involved overdoses,* ***the majority of persons with opioid addiction started with prescribed painkillers***." (Emphasis added). Of those who began abusing opioids in the 2000s, **75 percent reported that their first opioid was a prescription drug**.

404. Nine studies which included qualitative data on initiation into prescription opioid abuse were evaluated by Cicero and Ellis[285,286,287,288,289,290,291,292,293,294] in 2017 and **all nine described a legitimate prescription leading to addiction as a primary pathway to prescription opioid abuse**.[295] What was the driving force behind the increased prescribing of opioids?

405. One successful strategy utilized by states and local governments suing the opioid manufacturers for what U.S. District Judge Daniel Polster, appointed to oversee the federal multi-

[285] Cicero TJ, Ellis MS. The prescription opioid epidemic: a review of qualitative studies on the progression from initial use to abuse. Dialogues Clin Neurosci. 2017 Sep;19(3):259-269.
[286] Back SE, Lawson KM, Singleton LM, Brady KT. Characteristics and correlates of men and women with prescription opioid dependence. Addict Behav. 2011;36(8):829-834
[287] Daniulaityte R., Carlson RG., Kenne DR. Initiation to pharmaceutical opioids and patterns of misuse: preliminary qualitative findings obtained by the Ohio Substance Abuse Monitoring Network. J Drug Issues. 2006;36(4):787–808.
[288] Harocopos A., Allen B., Paone D. Circumstances and contexts of heroin initiation following non-medical opioid analgesic use in New York City. Int J Drug Policy. 2016;28:106–112.
[289] Lankenau SE., Teti M., Silva K., Jackson Bloom J., Harocopos A., Treese M. Initiation into prescription opioid misuse amongst young injection drug users. Int J Drug Policy. 2012;23(1):37–44.
[290] Merlo LJ., Singhakant S., Cummings SM., Cottier LB. Reasons for misuse of prescription medication among physicians undergoing monitoring by a physician health program. J Addict Med. 2013;7(5):349–353.
[291] Rigg KK., Murphy JW. Understanding the etiology of prescription opioid abuse: implications for prevention and treatment. Qual Health Res. 2013;23(7):963–975.
[292] St Marie B. Coexisting addiction and pain in people receiving methadone for addiction. West J Nurse Res. 2014;36(4):534–551.
[293] Stumbo SP., Yarborough BJ., McCarty D., Weisner C., Green CA. Patient-reported pathways to opioid use disorders and pain-related barriers to treatment engagement. J Subst Abuse Treat. 2017;73:47–54.
[294] Rigg KK, Ibanez GE. Motivations for non-medical prescription drug use: a mixed methods analysis. J Subst Abuse Treat. 2010;39(3):236-247.
[295] Back SE., Lawson KM., Singleton LM., Brady KT. Characteristics and correlates of men and women with prescription opioid dependence. Addict Behav. 2011;36(8):829–834.

district litigation (MDL) dealing with those suits against the opioid manufacturers and distributors, described as "…*a man-made plague, twenty years in the making*"[296], involved revealing the opioid companies' business practices as deceptive. In these fraud claims, often brought in connection with Medicare, Medicaid claims or consumer protection laws, governments charged that companies made **false and untrue representations about their products' addictiveness and effectiveness**, all calculated to mislead the state, prescribers, and the public. **This can be seen in many opioid manufacturer-sponsored programs presented by Medscape**.[297]

406. The marketing of OxyContin was particularly noteworthy: it included high-levels of targeted outreach to primary care physicians, outreach at national meetings, incentivized sales, and even illegal sales practices, all of which fueled multi-billion-dollar medication sales increases starting in the 1990s.[298] When Purdue Pharma introduced OxyContin in 1996, it was aggressively marketed and highly promoted. Sales grew from $48 million in 1996 to almost $1.1 billion in 2000[299] and the drug perennially ranked as Purdue's top seller, raking in a total of nearly $24 billion in revenues between 2010 and 2020.[300] The **Medical Letter on Drugs and Therapeutics** concluded in 2001 that oxycodone offered no advantage over appropriate doses of other potent opioids.[301] Purdue pursued an "aggressive" campaign to promote the use of opioids in general and

[296] U.S. District Judge, Daniel Polster, appointed to oversee the federal multi-district litigation (MDL) dealing with state and local governments suits against the opioid manufacturers and distributors, stated in refusing a motion from drug companies to dismiss the MDL lawsuit, "*It is accurate to describe the opioid epidemic as a man-made plague, twenty years in the making. The pain, death, and heartache it has wrought cannot be overstated*." (In Re: National Prescription Opiate Litigation, This Document Relates To: The Cty. of Summit, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 18-op-45090, No. 1:17-MD-2804, 2018 WL 6628898, at *21 (N.D. Ohio Dec. 19, 2018)).

[297] Haffajee RL, Mello MM. Drug Companies' Liability for the Opioid Epidemic. N Engl J Med. 2017 Dec 14;377(24):2301-2305.

[298] Compton WM. Jones CM. Epidemiology of the U.S. opioid crisis: the importance of the vector. Ann N Y Acad Sci. 2019 Sep; 1451(1): 130–143.

[299] "OxyContin Marketing Plan, 2002." Purdue Pharma, Stamford, CN, 2002.

[300] https://www.stamfordadvocate.com/business/article/As-Purdue-Pharma-prepares-to-dissolve-what-will-16452936.php#:~:text=OxyContin%20has%20perennially%20ranked%20as,to%20%241%20billion%20in%202020. (Accessed May 13, 2023).

[301] Oxycodone and OxyContin. Med Lett Drugs Ther 2001;43:80–81.

OxyContin in particular.[302,303,304,305,306,307,308] In 2001 alone, the company spent $200 million in an array of approaches to market and promote OxyContin.[309]

407. Purdue promoted among primary care physicians a more liberal use of opioids, particularly sustained-release opioids.[310] Primary care physicians began to use more of the increasingly popular OxyContin; by 2003, nearly half of all physicians prescribing OxyContin were primary care physicians.[311]

408. However, Purdue Pharma was not alone in promoting the expansive use of opioids by family doctors and primary care physicians. Marketing activities by all opioid manufacturers have been credited with fueling more frequent prescribing in primary care and promoting the expansion of use of their products to common chronic non-cancer pain conditions.[312,313] WebMD and Medscape were only more than happy to accommodate the opioid manufacturers' marketing needs.

409. For example, in June of 2015, Medscape offered a 'Commentary' titled '**Should We Prescribe Opioids for Chronic Pain?**' by Charles E. Argoff, MD.[314] This program is also still available for viewing in 2023. Dr. Argoff disclosed that he has served as a "…*director, officer,*

[302] "OxyContin Marketing Plan, 2002." Purdue Pharma, Stamford, CN, 2002.
[303] "OxyContin Marketing Plan, 1996." Purdue Pharma, Stamford, CN.
[304] "OxyContin Marketing Plan, 1997." Purdue Pharma, Stamford, CN.
[305] "OxyContin Marketing Plan, 1998." Purdue Pharma, Stamford, CN.
[306] "OxyContin Marketing Plan, 1999." Purdue Pharma, Stamford, CN.
[307] "OxyContin Marketing Plan, 1996." Purdue Pharma, Stamford, CN.
[308] "OxyContin Marketing Plan, 2001." Purdue Pharma, Stamford, CN.
[309] "OxyContin: balancing risks and benefits," in Hearing of the Committee on Health, Education, Labor, and Pensions, United States Senate, February 12, 2002, p 87 (testimony of Paul Goldenheim, Purdue Pharma).
[310] Zee AV. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am J Public Health. 2009 February; 99(2): 221–227.
[311] Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem. Washington, DC: General Accounting Office; December 2003. Publication GAO-04-110.
[312] Hadland SE, Cerda M, Li Y, Krieger MS, Marshall BDL. Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing. JAMA Intern Med. 2018;178(6):861–3.
[313] Van Zee A. The promotion and marketing of oxycontin: commercial triumph, public health tragedy. Am J Public Health. 2009;99(2):221–7.
[314] Argoff CE. Should We Prescribe Opioids for Chronic Pain? Medscape Commentary. https://www.medscape.com/viewarticle/846267#vp_2. (Accessed May 11, 2023).

partner, employee, advisor, consultant, or trustee for Teva,[315] *Daiichi Sankyo*[316]*, Pfizer,*[317] *Nectar Pharma,*[318] *Purdue Pharma,*[319] *Depomed,*[320] *Xenoport,*[321] *Iroko*[322]*, and Acorda*."[323] Dr. Argoff has

[315] Teva, an Israel-based drug manufacturer, makes Actiq and Fentora, which are branded fentanyl products for cancer pain, and a number of generic opioids including oxycodone. Attorney General Reaches $33.3 Million Agreement with Teva, Allergan; Opioid Makers Agree to Restrictions on Sales, Marketing. December 22, 2022. https://www.doj.nh.gov/news/2022/20221222-opioid-settlement.htm#:~:text=Teva%2C%20an%20Israel%2Dbased%20drug,of%20generic%20opioids%20including%20oxycodone. (Accessed March 21, 2023). Between 2013 and 2015 **Teva Pharmaceuticals USA, Inc. paid $336,863 in 'opioid related payments' to physicians in the State of New York.** Follow the Money: Pharmaceutical Manufacturer Payments and Opioid Prescribing Patterns in New York State. NYS Health Foundation. https://nyhealthfoundation.org/wp-content/uploads/2018/06/following-the-money-pharmaceutical-payments-opioid-prescribing-june-2018.pdf (Accessed May 11, 2023).

[316] Daiichi Sankyo produces several dosages of oxycodone tablets. https://www.daiichisankyo.com/media/press_release/detail/index_3329.html. (Accessed May 11, 2023).

[317] Pfizer actively promotes only one opioid painkiller, Embeda, which it acquired when it bought King Pharmaceuticals in 2011. https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022321s016lbl.pdf. (Accessed May 11, 2023).

[318] Nectar Remedies Ltd. manufacturers Tramanec 50mg tablet, an opioid analgesic. https://www.practo.com/medicine-info/tramanec-50-mg-tablet-31967. (Accessed May 11, 2023).

[319] Purdue and the Sackler family reached a $6 billion OxyContin settlement with state attorney generals in March, 2022.https://www.npr.org/2022/03/03/1084163626/purdue-sacklers-oxycontin-settlement#:~:text=Press-,Purdue%20Pharma%20and%20the%20Sackler%20family%20reach%20%246%20billion%20OxyContin,immunity%20from%20civil%20opioid%20lawsuits. (Accessed March 21, 2023). Between 2013 and 2015 **Purdue Pharma L.P. paid $591,611 in 'opioid related payments' to physicians in the State of New York**. Follow the Money: Pharmaceutical Manufacturer Payments and Opioid Prescribing Patterns in New York State. NYS Health Foundation. https://nyhealthfoundation.org/wp-content/uploads/2018/06/following-the-money-pharmaceutical-payments-opioid-prescribing-june-2018.pdf (Accessed May 11, 2023).

[320] Depomed, Inc. manufactures the opioids Nucynta and Lazanda. Between 2013 and 2015 **Depomed paid $189,634 in 'opioid related payments' to physicians in the State of New York**. Follow the Money: Pharmaceutical Manufacturer Payments and Opioid Prescribing Patterns in New York State. NYS Health Foundation. https://nyhealthfoundation.org/wp-content/uploads/2018/06/following-the-money-pharmaceutical-payments-opioid-prescribing-june-2018.pdf (Accessed May 11, 2023).

[321] Xenoport manufactures the non-opioid pain reliever, gabapentin.

[322] Iroko Pharmaceuticals manufactures a non-opioid non-steroidal anti-inflammatory.

[323] Acorda Therapeutics manufactures a non-opioid therapy for neurological conditions.

also been a speaker, or a member of a speakers' bureau, for Janssen,[324] Allergan,[325] Depomed,[326] Xenoport,[327] and Iroko.[328] Furthermore, Dr. Argoff also disclosed that he had received research grants from Forest Laboratories, Inc.,[329] Endo Pharmaceuticals[330] and Eli Lilly, which does not manufacture an opioid medication, although it makes a medication for opioid-induced constipation.

In '**Should We Prescribe Opioids for Chronic Pain?**' Dr. Argoff argues,

> "*Should providers prescribe opioid therapy for certain individuals with chronic pain? 'Should we prescribe' is not really the right question. What we need to ask ourselves is, how well are we prepared to prescribe opioids to our patients to provide the greatest benefits with minimal risks*?"

[324] Janssen developed two prescription opioid medicines – a patch and a crush-resistant tablet – designed to help patients suffering from pain. DURAGESIC®, NUCYNTA®, and NUCYNTA® ER. Johnson & Johnson and its U.S.-based Janssen Pharmaceutical Companies announced a settlement agreement with the State of New York and its participating subdivisions, including Nassau County and Suffolk County, resolving their opioid-related claims against the Company for $263 million. https://www.jnj.com/johnson-johnson-reaches-opioid-settlement-agreement-with-new-york-state-consistent-with-terms-of-previously-announced-broader-settlement-agreement-in-principle#:~:text=Janssen%20developed%20two%20prescription%20opioid,in%20the%20U.S.%20since%20launch. (Accessed March 21, 2023). Between 2013 and 2015 **Janssen Pharmaceuticals, Inc., paid $205,174 in 'opioid related payments' to physicians in the State of New York.** Follow the Money: Pharmaceutical Manufacturer Payments and Opioid Prescribing Patterns in New York State. NYS Health Foundation. https://nyhealthfoundation.org/wp-content/uploads/2018/06/following-the-money-pharmaceutical-payments-opioid-prescribing-june-2018.pdf (Accessed May 11, 2023).

[325] Ireland-based Allergan formerly made Norco- and Kadian-branded and generic opioids. Allergan will pay up to $2.37 billion to participating states and local governments over seven years. https://www.doj.nh.gov/news/2022/20221222-opioid-settlement.htm#:~:text=Ireland%2Dbased%20Allergan%20formerly%20made,Kadian%2Dbranded%20and%20generic%20opioids. (Accessed May 11, 2023).

[326] Depomed, Inc. manufactures the opioids Nucynta and Lazanda. Between 2013 and 2015 **Depomed paid $189,634 in 'opioid related payments' to physicians in the State of New York**. Follow the Money: Pharmaceutical Manufacturer Payments and Opioid Prescribing Patterns in New York State. NYS Health Foundation. https://nyhealthfoundation.org/wp-content/uploads/2018/06/following-the-money-pharmaceutical-payments-opioid-prescribing-june-2018.pdf (Accessed May 11, 2023).

[327] Xenoport manufactures the non-opioid pain reliever, gabapentin.

[328] Iroko Pharmaceuticals manufactures a non-opioid non-steroidal anti-inflammatory.

[329] Forest Laboratories manufactures Combunox, an oxycodone HCl and ibuprofen tablets. https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021378s006lbl.pdf (Accessed May 11, 2023).

[330] Endo Pharmaceuticals manufactured the opioid Opana ER, which it pulled from the market in 2017. In August 2022, Endo Pharmaceuticals agreed to pay the states $450 million over 10 years to support treatment and prevention of opioid use problems in addition to $2.75 million for archival expenses. The settlement will see Endo forgo opioid marketing forever. https://www.fiercepharma.com/pharma/endo-files-bankruptcy-signs-450m-settlement-following-other-opioid-makers-suit. (Accessed May 11, 2023).

410. In fact, in 2014, the year before Dr. Argoff's Medscape Commentary, the American Academy of Neurology published a position paper titled, '**Opioids For Chronic Noncancer Pain: A Position Paper of The American Academy of Neurology (AAN).**'[333] Therein, the AAN wrote, "*The risks for chronic opioid therapy for some chronic conditions such as headache, fibromyalgia, and chronic low back pain likely outweigh the benefits*."

411. The outsized impact on the opioid epidemic, the so-called "*man-made plague*", by WebMD/Medscape through Dr. Argoff and other speakers retained to discuss and promote the off-label, illegal, untruthful, and misleading use of opioids, as discussed above, may be best demonstrated through a reading of an August 29, 2013, office medical progress note written and electronically signed by Thomas Whitten, MD, with Westmoreland Pain Management Center, located in Greensburg, Pa[334] after he saw a Medscape program.

412. Dr. Whitten, discussing his patient "*with a history of left lower leg pain since a left total knee replacement*" but no documented evidence of cancer or cancer-related pain, indicates that the patient "*is recuperating quite well. She has titrated Subsys up to 600 mcg. Her insurer has upheld their denial of Subsys. The patient intends to pursue her appeal*."

413. It is important here to know that, upon receiving FDA approval to be marketed in 2012, Subsys was "…*indicated for the* ***management of breakthrough pain in cancer patients*** *18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*" and "…*may be dispensed only to patients enrolled in the TIRF REMS ACCESS program*."[335]

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[333] Franklin GM; American Academy of Neurology. Opioids for chronic noncancer pain: a position paper of the American Academy of Neurology. Neurology. 2014 Sep 30;83(14):1277-84.
[334] INSYS-MDL-008755449. (Accessed August 3, 2023).
[335] January 2012, Highlights of Prescribing. Subsys Product Insert. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202788Orig1s000lbl.pdf (Accessed August 3, 2023).

----------INDICATIONS AND USAGE----------
SUBSYS is an opioid agonist indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients must remain on around-the-clock opioids when taking SUBSYS. (1)
Limitations of Use:
SUBSYS may be dispensed only to patients enrolled in the TIRF REMS ACCESS program.

414. The requirement that the drug only be dispensed to patients enrolled in the TIRF REMS ACCESS program remains on the drug's product insert in 2022.[336]

415. While the August 29, 2013, progress note is silent as to whether the patient was enrolled in the TIRF REMS ACCESS program, as required, the progress note clearly states that the patient has "*…a history of left lower leg pain since a left total knee replacement",* but there is no evidence that the patient is experiencing breakthrough pain from cancer which is, ostensibly, why her insurer is denying coverage for Subsys.

416. Which begets the question: 'why would her physician, Dr. Whitten, treat her non-cancer-related, post-operative pain with Subsys', a form of fentanyl which has been described as "*approximately fifty times stronger than heroin and one hundred times more potent than morphine*?"[337] A drug which has been described by the Attorney General of New Jersey and Acting Director of the New Jersey Division of Consumer Affairs in 2017 as "…*one of the most dangerous consumer products on the market…"*[338]

417. Before ascertaining why Dr. Whitten would prescribe Subsys off-label for this patient's non-cancer-related, post-operative knee replacement pain, it is important to recall,

[336] https://www.drugs.com/pro/subsys.html (Accessed September 14, 2023).
[337] Complaint for Violation of the New Jersey False Claims Act, N.J.S.A. 2a: 32c-1, et seq. https://nj.gov/oag/newsreleases17/Insys-Complaint.pdf. (Accessed May 13, 2023).
[338] Id.

> "…*that selling Subsys only in compliance with its FDA-approved label would not generate the substantial revenue that it desired, (therefore)* ***Insys devised a subversive and illegal plan to promote Subsys for uses beyond the sole, narrow indication for which it sought and received FDA approval.***"[339]
>
> And,
>
> "*Insys knew, and, on information and belief, has always known, that exceptional Subsys sales could only be achieved by expanding the universe of patients prescribed Subsys* ***beyond the BTCP (break-through cancer pain) patient population*** *by (i)* ***misleading healthcare providers and patients about the safety and efficacy of off-label use****; and/or (ii) finding healthcare providers who cared less about patient safety than their own profits*."[340]

418. One key way in which Insys went about, **subversively and illegally, to promote Subsys for uses beyond the sole, narrow indication** for which it sought and received FDA approval and expand the universe of patients prescribed Subsys **beyond the break-through cancer pain patient population** was **by misleading healthcare providers and patients about the safety and efficacy of off-label use** and, for this, they relied, *inter alia*, upon Medscape.

419. In an October 5, 2017, complaint for violation of the New Jersey False Claims Act N.J.S.A. 2A: 32C-1, et seq., Christopher S. Porrino, Attorney General of New Jersey and Sharon M. Joyce, the Acting Director of the New Jersey Division of Consumer Affairs, described Insys Therapeutics, Inc., as,

> "…***a greedy pharmaceutical company****'s (with)* ***blatant disregard for the law and the health and safety of its consumers in favor of increased market share and maximized profits***" which "*peddles* ***one of the most dangerous consumer products on the market*** *- Subsys, an opioid-fentanyl drug approximately* ***fifty times stronger***

[339] Id.
[340] Id.

than heroin and one hundred times more potent than morphine."[341] (Emphasis Added).

420. Within this complaint, the State of New Jersey states that,

- "*Many afflicted by this (opioid) epidemic are first seduced by legally-prescribed pain medications. According to the National Institute on Drug Abuse,* ***eighty percent of new heroin users began their addictions by misusing prescription pain medications***.

- *"Fentanyl—a synthetic opioid analgesic fifty times stronger than heroin and a* ***hundred times more potent than morphine****—is* ***exacerbating the epidemic****. In March 2015, the United States Drug Enforcement Administration issued nationwide alerts that identified fentanyl as a significant threat to public health and safety*.

- *"It is part of a special class of drugs, known as transmucosal immediate release fentanyl ("TIRE"), which are approved by the Food and Drug Administration ("FDA") for the* ***single use of managing breakthrough cancer pain in patients who are tolerant to around-the-clock opioid therapy***. (Emphasis added).

- "*Cognizant that selling Subsys only in compliance with its FDA-approved label would not generate the substantial revenue that it desired, Insys devised a* ***subversive and illegal plan to promote Subsys for uses beyond the sole, narrow indication for which it sought and received FDA approval***.[342] (Emphasis added).

- "*Following FDA approval of its NDA (new drug application), a drug manufacturer, like Insys,* ***may not market and promote the drug for a non-approved indication or in a manner inconsistent with the drug's FDA-***

[341] Complaint for Violation of the New Jersey False Claims Act, N.J.S.A. 2a: 32c-1, et seq. https://nj.gov/oag/newsreleases17/Insys-Complaint.pdf (Accessed May 13, 2023).
[342] Id. at 1.

approved labeling, and its marketing and promotional materials may not contain false or misleading statements about the drug.[343] (Emphasis added).

- "*Insys knew, and, on information and belief, has always known, that* ***exceptional Subsys sales could only be achieved by expanding the universe of patients prescribed Subsys beyond the BTCP (break-through cancer pain) patient population by (i) misleading healthcare providers and patients about the safety and efficacy of off-label use****; and/or (ii) finding healthcare providers who cared less about patient safety than their own profits*."

421. Yet, Medscape afforded to Dr. Lex, in '**New Drugs and Devices From 2011 – 2012 That Might Change Your Practice**', the ability to pontificate that fentanyl was one of "…*10 medicines that we probably should know*…"[344]

422. On July 23, 2013, **one month before the progress note written by Dr. Whitten, and the same year the so-called 'third wave' of overdose deaths in the United States from opioids began**,[345] Medscape presented '**Cancer vs Noncancer Pain: Time to Shed the Distinction?**'[346], a commentary by, again, Charles E. Argoff, MD, a member of the Advisory Board of Medscape's 'Pain Learning Center'[347] and who received over $600,000 in payments from opioid manufacturers between 2013 and 2016.[348]

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[343] Id. at 9, citing 21 U.S.C.A. §§ 331, 352; 21 C.F.R. §314.81.

[344] Lex J. New Drugs and Devices From 2011 – 2012 That Might Change Your Practice. https://www.medscape.com/viewarticle/818206. (Accessed May 12, 2023).

[345] Centers for Disease Control and Prevention. Opioid Data Analysis and Resources. https://www.cdc.gov/opioids/data/analysis-resources.html#:~:text=The%20first%20wave%20began%20with,increasing%20since%20at%20least%201999.&text=The%20second%20wave%20began%20in,in%20overdose%20deaths%20involving%20heroin. (Accessed August 3, 2023).

[346] https://www.medscape.com/viewarticle/807780. (Accessed August 3, 2023). These trees

[347] https://www.medscape.org/resource/pain/ppc_staff (Accessed August 2, 2023).

[348] Fueling an Epidemic - Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups'. U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office. https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf (Accessed August 3, 2023).

423. In this Medscape Commentary, *Dr. Argoff* asks and states, *inter alia*,

> *"What exactly is the difference between chronic cancer-related pain and* ***chronic non-cancer-related pain****? Do we have a construct that we can use that helps us to distinguish that, and are we really helping ourselves in addressing the needs of our patients, and are we helping ourselves by making a clear dichotomy when the dichotomy may not exist in a chronic setting?* (Emphasis added).
>
> *"Training people to think about* ***cancer vs noncancer pain*** *is not, in my opinion, going to help them understand the important concepts of helping all people in as safe and effective a manner as possible.* (Emphasis added).
>
> *"We should address these concerns in a universal way, so that we are treating individuals and not categories, such as 'cancer' or 'noncancer,' that have no solid foundation or evidence base for being separate categories."*
>
> *"In summary, let's go beyond a simple dichotomy that has been around for too many years. Let's start to treat the people as they are -- incredibly complex, wonderful people who need our help in such a way that addresses their true needs, and not a false dichotomy that it is time to end."*[349]

424. Thus, Medscape and Dr. Argoff advocated dispensing with the "*simple dichotomy*" of 'cancer-related pain' versus 'non-cancer related pain' and, by extension, dispensing with the limitation on using opioids, even one such as Subsys, which is "*approximately fifty times stronger than heroin and one hundred times more potent than morphine*?" and "*…one of the most dangerous consumer products on the market…"* for non-cancer related pain.

425. Dr. Argoff's commentary, broadcast by Medscape is consistent with three of the ten themes ascertained by Goodwin et al as "*incongruent with federal guidelines and their goals*":

- Chronic pain is a common, under-treated problem.

[349] https://www.medscape.com/viewarticle/807780. (Accessed August 3, 2023). T

- Chronic pain is a chronic disease.
- Opioids are an appropriate treatment for chronic pain [84]

426. In it important to understand that Dr. Whitten's patient, as described within his August 2013 medical progress note, did *not* have cancer, let alone cancer-related 'breakthrough pain but, instead, post-operative pain following a left total knee replacement. However, Dr. Whitten, in August of 2013, one month after Medscape presented the biased 'commentary' by Dr. Argoff, writes within his progress note that, "*Her insurer has upheld their denial of Subsys. The patient intends to pursue her appeal*." [350] The reason his patient's insurer has denied payment for his patient's use of Subsys is because it's usage in this case is off-label: the patient did not have cancer-related breakthrough pain, the sole indication Insys Therapeutics, the manufacturer of Subsys, received from the FDA to legally market Subsys.[351]

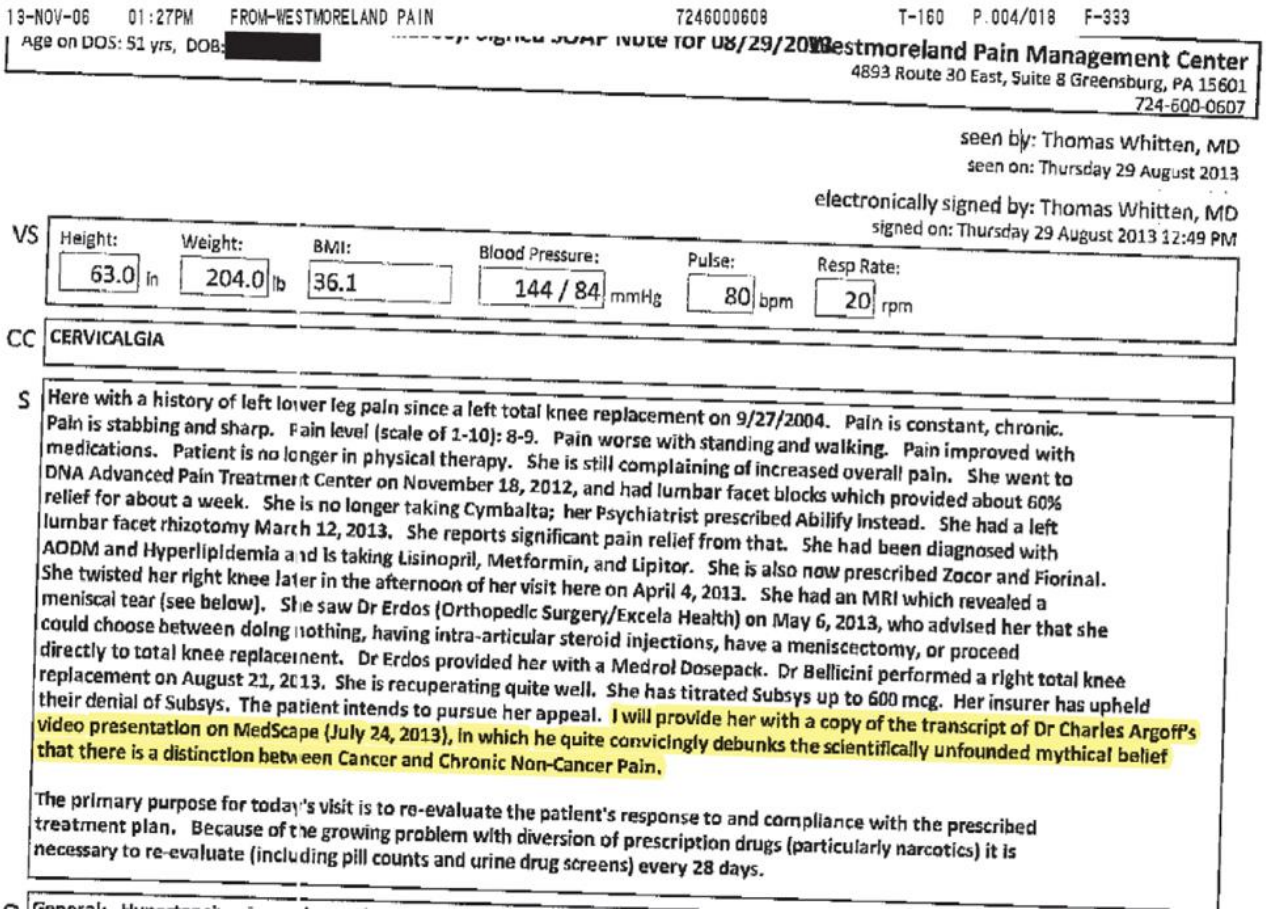
427. Dr. Whitten documents within his progress note,

> "***I will provide her with a copy of the transcript of Dr Charles Argoff's video presentation on Medscape (July 24, 2013)* (sic)*, in which he quite convincingly debunks the scientifically unfounded mythical belief that there is a distinction between Cancer and Chronic Non – Cancer Pain***."[352]

[350] INSYS-MDL-008755449. (Accessed August 3, 2023).

[351] In the October 5, 2017, complaint for violation of the New Jersey False Claims Act N.J.S.A. 2A: 32C-1, et seq., Christopher S. Porrino, Attorney General of New Jersey and Sharon M. Joyce, the Acting Director of the New Jersey Division of Consumer Affairs, described Insys Therapeutics, Inc., as, "…***a greedy pharmaceutical company's (with) blatant disregard for the law and the health and safety of its consumers in favor of increased market share and maximized profits***" which *"peddles one of the most dangerous consumer products on the market - Subsys, an opioid-fentanyl drug approximately fifty times stronger than heroin and one hundred times more potent than morphine*." (Emphasis Added).

[352] INSYS-MDL-008755449. (Accessed August 3, 2023).



13-NOV-06 01:27PM FROM-WESTMORELAND PAIN 7246000608 T-160 P.004/018 F-333

Age on DOS: 51 yrs, DOB: [redacted] ...Signed SOAP Note for 08/29/2013

Westmoreland Pain Management Center
4893 Route 30 East, Suite 8 Greensburg, PA 15601
724-600-0607

seen by: Thomas Whitten, MD
seen on: Thursday 29 August 2013

electronically signed by: Thomas Whitten, MD
signed on: Thursday 29 August 2013 12:49 PM

VS

Height:	Weight:	BMI:	Blood Pressure:	Pulse:	Resp Rate:
63.0 in	204.0 lb	36.1	144 / 84 mmHg	80 bpm	20 rpm

CC CERVICALGIA

S Here with a history of left lower leg pain since a left total knee replacement on 9/27/2004. Pain is constant, chronic. Pain is stabbing and sharp. Pain level (scale of 1-10): 8-9. Pain worse with standing and walking. Pain improved with medications. Patient is no longer in physical therapy. She is still complaining of increased overall pain. She went to DNA Advanced Pain Treatment Center on November 18, 2012, and had lumbar facet blocks which provided about 60% relief for about a week. She is no longer taking Cymbalta; her Psychiatrist prescribed Abilify instead. She had a left lumbar facet rhizotomy March 12, 2013. She reports significant pain relief from that. She had been diagnosed with AODM and Hyperlipidemia and is taking Lisinopril, Metformin, and Lipitor. She is also now prescribed Zocor and Fiorinal. She twisted her right knee later in the afternoon of her visit here on April 4, 2013. She had an MRI which revealed a meniscal tear (see below). She saw Dr Erdos (Orthopedic Surgery/Excela Health) on May 6, 2013, who advised her that she could choose between doing nothing, having intra-articular steroid injections, have a meniscectomy, or proceed directly to total knee replacement. Dr Erdos provided her with a Medrol Dosepack. Dr Bellicini performed a right total knee replacement on August 21, 2013. She is recuperating quite well. She has titrated Subsys up to 600 mcg. Her insurer has upheld their denial of Subsys. The patient intends to pursue her appeal. I will provide her with a copy of the transcript of Dr Charles Argoff's video presentation on MedScape (July 24, 2013), in which he quite convicingly debunks the scientifically unfounded mythical belief that there is a distinction between Cancer and Chronic Non-Cancer Pain.

The primary purpose for today's visit is to re-evaluate the patient's response to and compliance with the prescribed treatment plan. Because of the growing problem with diversion of prescription drugs (particularly narcotics) it is necessary to re-evaluate (including pill counts and urine drug screens) every 28 days.

428. This is direct and powerful evidence of the reach of Medscape's online CMEs, the reliance thereon by prescribers unaware of the 'incongruence of such an opioid-based presentation with federal guidelines and goals', and importantly, Medscape's contribution to an exacerbation of the opioid epidemic, the "*man-made plague*" as described by Judge Daniel Polster.

429. Another egregious example involves the opioid manufacturer, Collegium Pharmaceutical which markets the opioid 'Xtampza'. On **December 28, 2021**, Collegium Pharmaceutical reached a $2.75 million agreement with 27 U.S. cities, counties and subdivisions related to the opioid crisis and the company's sale of Xtampza.[353] However, on or about **December 16, 2021**, before the announcement of the $2.75 million settlement, Collegium

[353] https://www.biospace.com/article/collegium-pharmaceutical-reaches-opioid-settlement-with-u-s-government-/ (Accessed May 11, 2023).

was found to be marketing its Xtampza product as a **safe and responsible alternative to other opioids**, even though **it has the same active ingredient as Oxycontin and other opioids** and Collegium agreed to pay $185,000 to the State of Massachusetts.[354]

430. Under the settlement, Collegium also said **it will no longer sponsor "*speaker programs*" in which physicians promote Xtampza to other health care workers.** As stated in the 2021 'ASSURANCE OF DISCONTINUANCE PURSUANT TO G. L. C. 93A, SECTION 5', Commonwealth Massachusetts v. Collegium Pharmaceutical, Inc.,

> "'*Speaker Programs' means* ***any event****, including a breakfast, lunch, or dinner, sponsored by Collegium* ***at which a physician or other health care professional makes a speech or presentation to other health care professionals about a drug or a disease state***.'
>
> "*Collegium misled Massachusetts doctors about Xtampza's risks and appropriate uses, at various times, by deceptively marketing it as a safer and more responsible choice than other opioids and improperly marketing it to treat acute pain, primarily through In-Person Detailing and* ***Speaker Programs***."[355]

431. As such, a Collegium-sponsored Medscape presentation which, by definition, is made to "*other healthcare professionals*", during which the author(s) promote(s) Xtampza a "*safe and responsible alternative to other opioids, even though it has the same active ingredient as Oxycontin and other opioids*", is not only misleading, untruthful, false but also in violation of Collegium's 2021 settlement agreement with the Commonwealth of Massachusetts.

432. Despite the December 16, 2021, settlement with the Commonwealth of Massachusetts, on **January 5, 2022**, **just 20 days after signing the settlement**, Collegium

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354 https://www.cbsnews.com/boston/news/opioid-maker-collegium-pharmaceutical-agrees-to-stop-in-person-marketing-to-doctors/ (Accessed May 11, 2023).

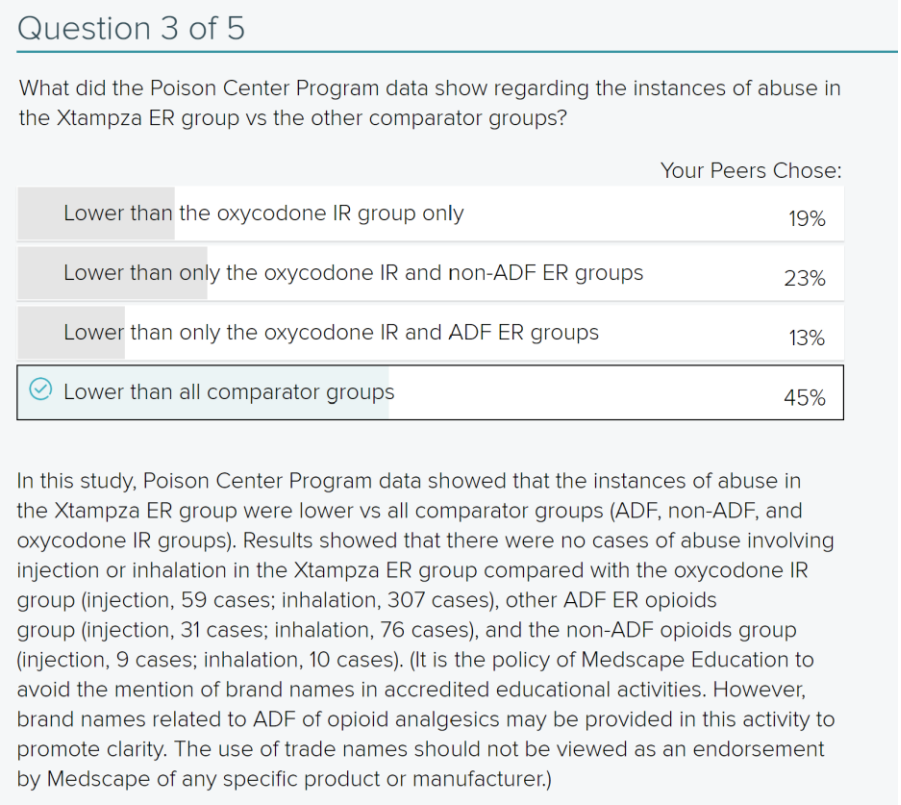
355 https://www.mass.gov/doc/collegium-assurance-of-discontinuance-2021-12-16/download at 3. (Accessed May 11, 2023).

financially supported Medscape's January 5, 2022, program, '**Abuse-Deterrent Formulations of Opioid Analgesics: Using Real-World Data for Clinical Decision-Making**' by Jody Green, PhD, and, once again, Charles Argoff, MD.[356]

433. In violation of the December 16, 2021, settlement agreement wherein Collegium agreed to stop "***deceptively telling doctors that Xtampza's abuse-deterrent formulation - which was designed to make Xtampza more difficult to crush or dissolve in water - could prevent intentional misuse, making Xtampza a "safe" and "responsible" choice***",[357] this Collegium-sponsored Medscape program finishes with follow-up questions and, as readily seen in question/answer 3 of 5 (below), directly compares Poison Center Program data regarding the instance of abuse in the Xtampza ER (extended release) group versus the other comparator groups.

[356] Abuse-Deterrent Formulations of Opioid Analgesics: Using Real-World Data for Clinical Decision-Making. Medscape Education Pharmacists. https://www.medscape.org/viewarticle/965886. (Accessed May 11, 2023).

[357] https://www.mass.gov/doc/collegium-assurance-of-discontinuance-2021-12-16/download at 4. (Accessed May 11, 2023).



Question 3 of 5

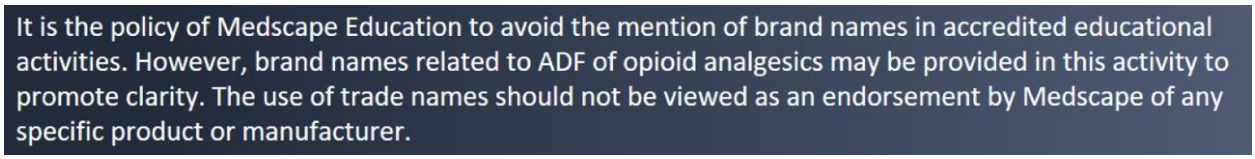
What did the Poison Center Program data show regarding the instances of abuse in the Xtampza ER group vs the other comparator groups?

	Your Peers Chose:
Lower than the oxycodone IR group only	19%
Lower than only the oxycodone IR and non-ADF ER groups	23%
Lower than only the oxycodone IR and ADF ER groups	13%
✓ Lower than all comparator groups	45%

In this study, Poison Center Program data showed that the instances of abuse in the Xtampza ER group were lower vs all comparator groups (ADF, non-ADF, and oxycodone IR groups). Results showed that there were no cases of abuse involving injection or inhalation in the Xtampza ER group compared with the oxycodone IR group (injection, 59 cases; inhalation, 307 cases), other ADF ER opioids group (injection, 31 cases; inhalation, 76 cases), and the non-ADF opioids group (injection, 9 cases; inhalation, 10 cases). (It is the policy of Medscape Education to avoid the mention of brand names in accredited educational activities. However, brand names related to ADF of opioid analgesics may be provided in this activity to promote clarity. The use of trade names should not be viewed as an endorsement by Medscape of any specific product or manufacturer.)

434. Medscape goes on to state that there were no cases of abuse involving injection or inhalation in the Xtampza ER group compared with the oxycodone IR (immediate release) group, other ADF ER opioids and other non-ADF opioids. This violates the Collegium agreement with the State of Massachusetts "…***by deceptively telling doctors that Xtampza's abuse-deterrent formulation - which was designed to make Xtampza more difficult to crush or dissolve in water - could prevent intentional misuse, making Xtampza a "safe" and "responsible" choice***."

435. Note the specific use of the brand name, 'Xtampza ER' by Medscape. However, in this Collegium-sponsored presentation Medscape claims that:



It is the policy of Medscape Education to avoid the mention of brand names in accredited educational activities. However, brand names related to ADF of opioid analgesics may be provided in this activity to promote clarity. The use of trade names should not be viewed as an endorsement by Medscape of any specific product or manufacturer.

436. Here, for its paying sponsor, Collegium, Medscape makes an exception and, in the presentation, Medscape specifically uses Xtampza ER and compares it to generic "*other oxycodone ER*" and "*oxycodone IR*".

437. In further violation of the December 16, 2021, settlement agreement, alongside slide 39/68 of this presentation, Dr. Green states,

> "*And what we saw was the **Xtampza ER**, which is another abuse deterrent formulation oxycodone product, **had the lowest rate of past 30 non-medical use compared to other oxycodone ER products** which includes OxyContin and other oxycodone IR products*."

448. In other words, Xtampza is safer than OxyContin. Which is exactly what Collegium agreed to NOT say when it signed the settlement agreement with the Massachusetts Attorney general just 20 days earlier.

449. Despite the settlement with the Massachusetts state Attorney General in December 2021, on **April 3, 2023**, Dr. Charles Argoff is back, this time with Lynn R. Webster, MD,[358] and pharmacist, Timothy J. Atkinson, PharmD. Together they co-authored a Medscape CME program titled, '**Opioid Analgesic Therapy for Chronic Pain: Defining Current Therapeutic Use'** which was "*[s]upported by an independent education grant from Collegium, Pharmaceutical*", released on April 3, 2023, and valid for CME credit through April 3, 2024.[359]

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[358] In 2010, Dr. Webster's Utah clinic was raided by the U.S. Drug Enforcement Administration. Dr. Webster acknowledged that as many as 20 former patients of his clinic have died of opioid overdoses. (Fauber, J. Top pain physician acknowledges patients' fatal overdoses. Milwaukee Journal Sentinel. February 19, 2013. https://archive.jsonline.com/watchdog/watchdogreports/top-pain-physician-acknowledges-patients-fatal-overdoses-o78m2jb-191945161.html/). As of 2018 he had been named as a defendant in more than 80 class action lawsuits along with pharmaceutical companies that manufactured opioids. Anson, Pat. "Prominent Pain Doctor Faces Hundreds of Lawsuits". Pain News Network. Retrieved November 15, 2021. https://www.painnewsnetwork.org/stories/2018/4/13/prominent-pain-doctor-faces-hundreds-of-lawsuits. (Accesse May 19, 2023).

[359] https://www.medscape.org/viewarticle/990330. (Accessed May 12, 2023).

450. Collegium's program here, which Medscape is more than happy to get paid to broadcast, indicates that Xtampza's abuse-deterrent formulation makes Xtampza a safe and responsible choice when compared to OxyContin and other ADF and Non-ADF opioids.

451. In slide 75/95, Dr, Webster favorably compares the oral pharmacokinetics (PK) [360] of manipulated and intact Xtampza ER to OxyContin, indicating that Xtampza ER's PK profile is safer 'as compared to OxyContin'.

> "*And you can see that the crushed OxyContin on the left, which is an immediate release, in the orange, and you see that Xtampza intact and crushed are very similar; they didn't shift more to the left which is a more immediate release type of formulation. Whereas, on the right, you see the crushed OxyContin and intact OxyContin are basically the same. Once it is manipulated, it shifts all the way over and this is what made it so attractive for so long to the people who were seeking a higher dose for a more powerful effect for whatever reason.* ***But the point here is that the Xtampza did provide some barrier to that immediate release****. Not that it still can't be abused*." (Emphasis added).

458. In this presentation, Collegium, through Medscape, is not only violating the settlement agreement signed with the State of Massachusetts but is now "*deceptively telling*" doctors throughout the entire country that "*Xtampza's abuse-deterrent formulation - which was designed to make Xtampza more difficult to crush or dissolve in water - could prevent intentional misuse, making Xtampza a "safe" and "responsible" choice.*

459. This representation by Medscape is patently false, untruthful, and misleading for, as stated within the agreement with the State of Massachusetts, "***Xtampza has the same active ingredient (oxycodone) with the same risk of addiction, overdose, and death***" as does OxyContin.

[360] The activity of drugs in the body over a period of time, including the processes by which drugs are absorbed, distributed in the body, localized in the tissues, and excreted. National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/pharmacokinetics. (Accessed May 12, 2023).

(1) Medscape and the REMS Program Companies (RPC)

460. As this Complaint describes in detail, Medscape played a significant role in contributing to the opioid epidemic in this country, an epidemic which, in addition to the toll on families and loved ones, imposes significant economy-wide costs. After she was terminated, Relator Dr. Saenger used her knowledge about Medscape to figure out, and document, the techniques her former company used, and continues to use, to secretly promote drugs off-label, and measure the impact of these promotions using embedded material. This led her to discover that in 2011, Pfizer and Purdue Pharma funded a confidential plan to educate more than 650,000 prescribers about opioids. The plan involved forming a consortium of opioid manufacturers to sponsor free, or low-cost, biased education for prescribers.

461. In 2012, the FDA mandated that opioid companies provide CME to prescribers on Extended-Release Long-Acting (ER/LA) opioids. This CME was to adhere to the FDA's Blueprint (curriculum), a document created with input from varied stakeholders, including industry. Before this Blueprint went into effect, Pfizer and Purdue started to create a consortium of opioid companies (the REMS Program Companies, or RPC) to sabotage the FDA's goal of reducing inappropriate prescribing of opioids.[361]

462. Specifically, the RPC funded CME on opioids using CE providers who were members of CO*RE (the Collaborative for REMS Education). CO*RE consisted of about a dozen CE providers, including Medscape. It also included the president of a market research company, defendant Healthcare Performance Consulting (HPC), which had partnered with Medscape to promote unapproved uses for other drugs in Medscape CE. Originally, CO*RE also included the

[361] https://www.asam.org/docs/default-source/advocacy/letter-to-hhs-assistant-secretary-for-planning-and-evaluation-regarding-mandatory-prescriber-education-may-20-2015.pdf?sfvrsn=0.

American Pain Society, which helped set up CO*RE. However, the Society went bankrupt after a Senate investigation into its connections to five opioid manufacturers.[362]

463. The prescriber education funded by the Consortium to cover the ER/LA opioid Blueprint, and later, all opioids, contains significant false claims. Relator Elizabeth Saenger, PhD's discovery of these claims in content published by Medscape, LLC, of WebMD, her former employer, was facilitated by market research from the Consortium.

464. Pfizer and Purdue hired Healthcare Performance Consulting to embed in CME presentation information favorable to their products to effect behavior change. The Relator was familiar with examples of HPC's work in promoting unapproved uses in this way due to its collaboration with Medscape, so she was able to find a confidential copy of the **Needs Assessment and Educational Design Report: Long-Acting and Extended-Release Analgesic Opioids REMS**.[365]

465. The HPC Needs Assessment draws on surveys sent to more than 50,000 clinicians; forty ninety-minute interviews with prescribers; a literature review; programmatic research; and a belief in the value of large-scale CME collaboration, such as Pfizer's 'CS2Day' in China, a smoking cessation initiative.[366] The HPC report also states that the enterprise will measure results to make mid-course corrections.[367]

466. The results of the first 30 CME programs indicated how many prescribers had changed their behavior in each of several categories, such as:

- Assessing patients for treatment with ER/LA opioid analgesic therapy (17%)

[362] https://www.theguardian.com/us-news/2019/may/25/american-pain-society-doctors-painkillers. (Accessed September 20, 2023).
[365] Id.
[366] https://pubmed.ncbi.nlm.nih.gov/22190099/ (Accessed September 20, 2023).
[367] https://img.medscapestatic.com/pi/edu/qrcode/posters/interim-analysis-of-practice-changes-opioid-rems-programs.pdf (Accessed September 20, 2023).

- Initiating, modifying, or discontinuing treatment with ER/LA analgesics (14%)
- Managing risks of patients prescribed ER/LA opioid analgesics (17%)[368]

467. The results also indicated what barriers clinicians or opioid companies faced in sales, such as, "*Some patients are concerned that they may become dependent on or addicted to opioids*."[369] These barriers to sales are identified so that CO*RE's 'educational designers' can overcome them. Specifically: "*Knowledge of the nature and magnitude of these barriers helps educational designers address them within the scope of the interventions [CE], thereby facilitating changes in clinician performance as compared to changes in knowledge."*[370]

468. CO*RE retained four nationally recognized experts in educational design, including the prominent Donald E. Moore, Jr, PhD. These experts specialize in, "*evidence-based educational strategies that are proven to change clinician behavior*." The four experts guided the development of CO*RE's CME by working with small groups (two for primary care, and two for subspecialty care) to advance CO*RE's goal of, "*changing clinician behavior in the short- and long-term*."[371]

469. These CO*RE experts and members based their curriculum on a CME text funded by Endo Pharmaceuticals. The text, *Responsible Opioid Prescribing: A Guide for Michigan Physicians*, was authored by Scott M. Fishman, MD, discussed supra.

470. The text is designed to increase the prescribing of opioids, concluding: *There is no debate among public health experts about the undertreatment of pain, which has been recognized as a public health crisis for decades. The cost of undertreated pain in dollars is astronomical, but*

[368] https://img.medscapestatic.com/pi/edu/qrcode/posters/interim-analysis-of-practice-changes-opioid-rems-programs.pdf (Accessed September 20, 2023).
[369] https://img.medscapestatic.com/pi/edu/qrcode/posters/interim-analysis-of-practice-changes-opioid-rems-programs.pdf
[370] https://www.asam.org/docs/default-source/advocacy/letter-to-hhs-assistant-secretary-for-planning-and-evaluation-regarding-mandatory-prescriber-education-may-20-2015.pdf?sfvrsn=0, at 53.
[371] https://www.asam.org/docs/default-source/advocacy/letter-to-hhs-assistant-secretary-for-planning-and-evaluation-regarding-mandatory-prescriber-education-may-20-2015.pdf?sfvrsn=0. at p. 35.

the cost in human suffering is immeasurable. Turning away from patients in pain simply is not an option."[372]

471. RPC also introduced false claims into RPC-funded CME. Here are examples of four kinds of false claims: false claims about safety (risk), false claims about Patient-Provider Agreements, also known as Opioid Treatment Agreements, false claims about the efficacy of opioids; and false claims about the benefits of opioids.

472. As noted earlier, Medscape CME minimized the potential danger of opioids by claiming that healthcare professionals can stratify (differentiate) patients who are low-risk vs high-risk for addiction, overdose, or diversion, and prescribe opioids only for the former. Medscape even encourages prescribers to download alleged risk stratification tools from a section of an RPC-funded online page.

473. For example, **Opioid Prescribing - Safe Practice, Changing Lives**[373] presents a table summarizing several screening tools and says:

> "*A variety of self-administered and provider-administered screening tools are helpful for risk stratification…. Many practices have a risk assessment tool in their electronic health record (EHR) system. If you are not already using one of these tools, check your EHR system to see if it has one in place*."

469. In sharp contrast, however, the 2016 CDC guideline states, in its review of the literature:

> "*No study evaluated the effectiveness of risk mitigation strategies (use of risk assessment instruments, opioid management plans, patient education, urine drug testing, use of PDMP [Prescription Drug Monitoring Program] data, use of monitoring instruments, more frequent monitoring intervals, pill counts, or use of*

[372]Fishman SM. Responsible Opioid Prescribing: A Guide for Michigan Physicians. Waterford Life Sciences: Washington, DC. Released 2009 at p. 105

[373] https://www.medscape.org/viewarticle/892209 (Accessed September 20, 2023).

abuse-deterrent formulations) for improving outcomes related to overdose, addiction, abuse, or misuse."

470. In other words, there is no study or tool that can legitimately allay prescriber fears regarding the risk of addiction, overdose, and diversion – the barriers to prescribing mentioned earlier.

471. In their 2021 publication, '**Increase your Confidence in Opioid Prescribing: Marketing Messages in Continuing Medical Education Activities on ER/LA Opioids,**[84] Goodwin et al. confirmed the findings of the Relator. Seeking to determine whether industry-funded REMS on long-acting opioids were consistent with the FDA's goal to reduce serious, adverse outcomes resulting from inappropriate prescribing, misuse, and abuse, these researchers, in 2018, analyzed all internet-based REMS CME activities funded by the REMS Program Companies (RPC), a consortium of ER/LA opioid manufacturers. They utilized "…*systematic narrative thematic analysis, an inductive approach that allows for mapping of concepts and meanings across a body of data by identifying, recording, analyzing, and refining key narrative points, called 'themes'*."[374]

472. Ten themes were identified, all of which were somewhat to seriously **incongruent with federal guidelines and their goals**:

- **Chronic pain** is a common, under-treated problem.
- **Chronic pain** is a chronic disease.
- **Opioids are an appropriate treatment for chronic pain**.
- ER/LAs are more appropriate than immediate-release (IR) opioids for **chronic pain**.

[374] Id.

- Tolerance is normal, expected, and beneficial.
- "Opioid rotation" can maximize analgesia and minimize adverse effects.
- There is no population for whom opioids are absolutely contraindicated or inappropriate.
- Screening and monitoring tools are effective for preventing opioid-related problems. Opioid related adverse effects, such as respiratory depression and addiction, are due only to misuse and abuse.
- Addiction, overdose, and death are due to street drugs such as heroin and fentanyl, not prescription opioids.

473. Themes and statements repeated in these activities contradicted current medical knowledge, evidence-based federal guidelines, and FDA goals.

474. As discovered by the Relator, Elizabeth Saenger, and confirmed by Goodwin et al., some activities described opioids as the most effective medication for chronic pain; others described opioids as "*one of many tools in the toolbox*." Goodwin et al. write in their peer-reviewed medical article that "***A Medscape activity*** *states, 'The initial therapeutic trial of an ER/LA opioid may last from several weeks to* ***several months*****'**.[375] (Emphasis added).

475. This Medscape presentation, '**Opioid Prescribing: Safe Practice, Changing Lives - 2018 Update**', released March 28, 2018, reviewed and renewed May 9, 2019, valid for CME credit through August 31, 2019, and still accessible in 2023, was "*sponsored by an independent educational grant from ER/LA Opioid Analgesic REMS Program Companies.*"[376]

476. They concluded that *"(I)ndustry-funded REMS-compliant CME on opioids contain messages that misrepresent scientific evidence and may foster overprescribing of opioids*." And, as pointed out in detail herein by the Relator, Medscape consistently misrepresented the scientific

[375] www.medscape.org/viewarticle/892209.
[376] Medscape was a member of C*ORE which provides CME funded by the RPC, a consortium of (now) about 65 opioid companies.

evidence leading to an increased number of prescribers determine, post-presentations, to **change their prescribing habits and prescribe opioids off-label, both in dosage and condition**.

477. CO*RE originally aimed to educate 650,000 HCPs about opioids; as of today, it has "reached more than 750,000 professionals who prescribe opioids."

478. Despite an absence of evidence to support risk mitigation strategies, RPC-funded CME also praises several alleged risk mitigation tools. For example, it promotes the ORT [Opioid Risk Tool], a five-item, paper-and-pencil quiz patients can conveniently take in the physician's waiting room, claiming it has "*good content, face, and construct validity*." It repeats that assessment in several programs, and sometimes more than once in the same program.

479. The CDC review of the literature, on the other hand, states, "*Results for the Opioid Risk Tool (ORT) (89–91) were extremely inconsistent*…" Later, a 2018 study tried to replicate the ORT results in an academic pain management center.[377] It concluded:

> "*Although the ORT was designed as a fast, simple stratification tool to assess patients' future potential for abuse, misuse, and diversion of opioid medications, in this pain population,* ***the ORT risk assessment was no better than chance when used as a self-report tool***." (Emphasis added).

480. A revised ORT[378], the ORT-OUD, has even more egregious problems, although a slide once linked to **Pain Management and Opioids: Balancing Risks and Benefits-Updated 2019-20**[379] claims, in a false, and somewhat confusing way that:

> "*The original ORT was validated throughout the world in many cultures, countries and languages. Researchers still need time to determine the validity and reliability*

[377] Clark, Meredith & Hurley, Robert & Adams, Meredith. (2018). Re-assessing the Validity of the Opioid Risk Tool in a Tertiary Academic Pain Management Center Population. Pain medicine (Malden, Mass.). 19. 10.1093/pm/pnx332.
[378] Cheatle MD, Compton PA, Dhingra L, Wasser TE, O'Brien CP. Development of the Revised Opioid Risk Tool to Predict Opioid Use Disorder in Patients with Chronic Nonmalignant Pain. J Pain. 2019 Jul;20(7):842-851.
[379] https://www.medscape.org/viewarticle/917714 (Accesses September 20, 2023)

of the ORT-OUD in various races and ethnicities, but at this point, the revised ORT-OUD is the ***best tool available***." (Emphasis added).

481. The "*best tool available*" is based on a study with a very non-random sample.[380] It excluded many groups, such as those recently hospitalized for substance abuse, who would be most at risk for opioid use disorder. Instead, it included patients at much less risk for opioid risk disorder such as people on low doses of short-acting opioids for a brief period of time, and it did not follow them for very long. When this study is uncritically used to recommend the use of the ORT-OUD, clinicians will feel, mistakenly, that they are safer in prescribing opioids than they really are.

482. An antidote to the false security clinicians may get from the tools touted in CME may be those statistics published within a 2016 article published in the England Journal of Medicine: "*Rates of carefully diagnosed addiction have averaged less than 8% in published studies, whereas rates of misuse, abuse, and addiction-related aberrant behaviors have ranged from 15 to 26%*."[381] However, RPC-funded CME for opioid prescribers fails to include any of these figures.

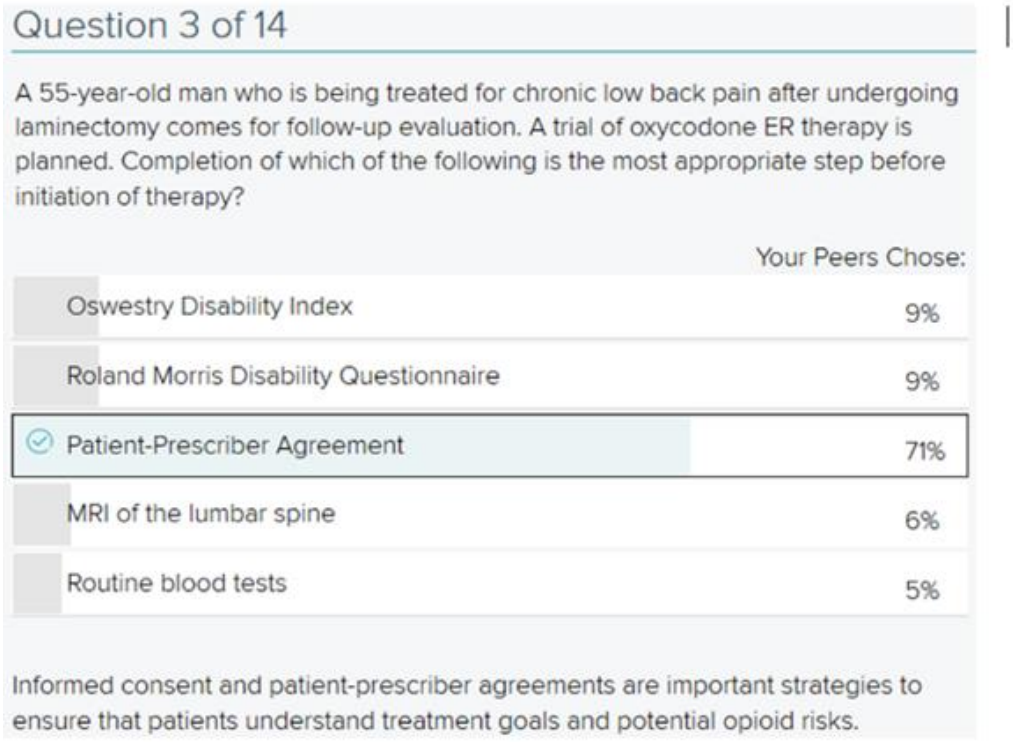
483. A second false claim in RPC-funded CE concerns Patient-Provider Agreements. For example, **Achieving Safe Use While Improving Patient Care**[382] states:

"*Written documentation in the form of a patient-prescriber agreement (PPA), which is signed by both the patient and provider at the time an opioid is prescribed, can help clarify the management plan with the patient, the patient's family, and other clinicians who may become involved in the patient's care. PPAs can help ensure that patients and caregivers understand the goals and risks of treatment and*

[380] Cheatle MD, Compton PA, Dhingra L, Wasser TE, O'Brien CP. Development of the Revised Opioid Risk Tool to Predict Opioid Use Disorder in Patients with Chronic Nonmalignant Pain. J Pain. 2019 Jul;20(7):842-851.
[381] Volkow ND, McLellan AT. Opioid Abuse in Chronic Pain--Misconceptions and Mitigation Strategies. N Engl J Med. 2016 Mar 31;374(13):1253-63.
[382] https://www.medscape.org/viewarticle/807608 (Accessed September 20. 2023)

how to use these medications safely. For patients at higher risk for opioid misuse, clear written guidelines may be particularly helpful in reinforcing expectations about safe use."

484. A quiz question embedded within this program measures the extent to which clinicians absorb this message about the value of PPAs. This is useful market research data.



485. However, a 2017 analysis of these tools concludes[383]:

"*Evidence to support the role of OTAs [Opioid Treatment Agreements] in decreasing the misuse of opioids is relatively weak; improvements to neither adherence, patient care, nor the rights of both patients and physicians have been proven after the use of OTAs (Refs). One systematic review failed to reveal any high quality studies regarding opioid misuse outcomes in association with UDT [urine*

[383] Calixto F, Beakley BD, Galan V, et al. Prescription Opioid Abuse in Chronic Pain: An Updated Review of Opioid Abuse Predictors and Strategies to Curb Opioid Abuse (Part 2). Pain Physician. 2017;20;S111-S133.

drug testing] and treatment agreements in patients with CNCP [chronic non-cancer pain]. Every study was observational and had a poor to fair grade; opioid misuse decreased slightly (7-23%) following a treatment agreement in the presence or absence of UDT (Ref)."

486. It is important to also note that oxycodone ER (OxyContin, Purdue) is off-label for chronic back pain, but a mention of this use is slipped into the question.

487. RPC-funded Medscape CME also makes false claims regarding the efficacy of opioids in treating chronic back pain. For example, one case history promoted Purdue's OxyContin, an extended-release form of oxycodone, for chronic back pain, a very common cause of disability.[384] This off-label use, featured in multiple presentations and online at Medscape, is not the first line (nor the best) treatment recommended by the both the CDC's 2016 guidelines[385] and the 2022 'update'.[386]

438. A detailed example of this was made available through Medscape[387] and, *inter alia,* discussed the case of the fictional patient, "Ernesto".[388] The 'presentation' is still available to be read, downloaded, and be relied upon in 2023. No changes have been made in the presentation since its initial presentation in 2015 despite publication of Guidelines regarding prescribing opioids by the CDC in 2016 and updated in 2022 and discussed below.

439. The participants of the REMS on Medscape are informed that 'Ernesto' "*sustained (a) workplace back injury at age 41 (which) causes* ***chronic back pain***." (Emphasis Added). He

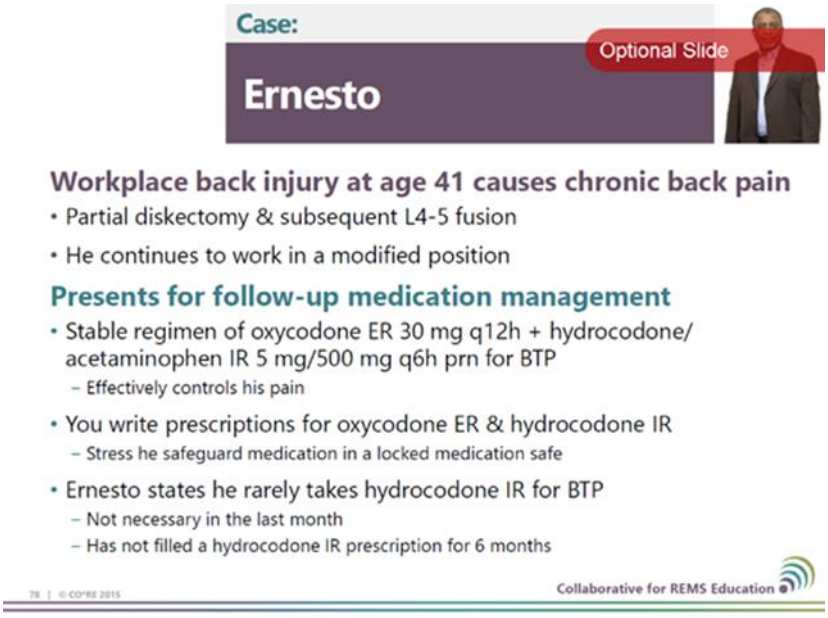
[384] ER/LA OPIOID REMS: Achieving Safe Use While Improving Patient Care. Presented by CO*RE Collaboration for REMS Education. (Slides 78-83). https://img.medscapestatic.com/images/841/340/841340_core_cd.pdf. (Accessed May 12, 2023).
[385] CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. Morbidity and Mortality Weekly Report (MMWR). Recommendations and Reports / March 18, 2016 / 65(1);1–49.
[386] CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. Morbidity and Mortality Weekly Report (MMWR). Recommendations and Reports / November 4, 2022 / 71(3);1-95.
[387] https://img.medscapestatic.com/images/841/340/841340_core_cd.pdf. (Accessed May 12, 2023).

[388] Id. at slides 78-83.

underwent a "*partial diskectomy & subsequent L4-5 fusion*." He "*presents for follow-up medication management*" and the participant is informed that the patient, Ernesto, is on a "*[s]table regimen of oxycodone ER*[390] *(*extended release*) 30 mg q12h + hydrocodone/ acetaminophen IR (*immediate release*) 5 mg/500 mg q6h (every 6-hours) prn (as needed) for BTP (break through pain)*" which "*effectively controls his pain*."

488. The 'participant' is informed that "*Ernesto states* ***he rarely takes hydrocodone IR for BTP – Not necessary in the last month – Has not filled a hydrocodone IR prescription for 6 months***."

[390] OxyContin is a brand-name version of the extended-release form of oxycodone.



489. Yet, the participant is informed that he/she, the participant "…*write prescriptions for oxycodone ER* ***and*** *hydrocodone IR*."[391] (Emphasis Added).

You write prescriptions for oxycodone ER & hydrocodone IR
– Stress he safeguard medication in a locked medication safe

Ernesto states he rarely takes hydrocodone IR for BTP
– Not necessary in the last month
– Has not filled a hydrocodone IR prescription for 6 months

490. It needs to be noted that, upon presentation, 'Ernesto' is prescribed a total of 1,800 mg of oxycodone ER and 600 mg of hydrocodone/acetaminophen IR (despite sharing that he "*rarely takes*" the immediate release formulation of the drug.)

[391] ER/LA OPIOID REMS: Achieving Safe Use While Improving Patient Care. Presented by CO*RE Collaboration for REMS Education at 78. https://img.medscapestatic.com/images/841/340/841340_core_cd.pdf. (Accessed May 12, 2023).

491. The participant is then provided with a "**Taper Schedule" for Month 1**".[392] The 'recommended taper schedule' for this patient with improving back pain includes "*oxycodone ER 20 mg q12h (#60) + oxycodone IR 5 mg (#60) (with) instructions*."[393]

492. The participant is recommended to write a prescription for sixty 20 mg extended release oxycodone in addition to sixty 5 mg immediate release pills even after the REMS presentation informs the participant that the patient has already stated that he "***rarely takes ...(which has) [n]ot (been) necessary in the last month…(and he)…[h]as not filled a hydrocodone IR prescription for 6 months***." (Emphasis Added)

493. For 'Ernesto's' 'Taper Schedule – Month 2', while currently prescribed oxycodone ER 40 mg/day *in addition* to the 60 immediate release pills, those involved with the development of this REMS, including Purdue Pharmaceuticals, advocate prescribing another 60 pills now of 10 mg oxycodone *in addition now to* **ninety immediate release 5 mg pills of oxycodone**. Again, this presentation was first made available on Medscape in 2015 and **remains there to this day for any prescriber to see**.

494. Of significance, this sponsored story of 'Ernesto' **fails to mention recommending non-opioid therapy including exercise** (aerobic, aquatic, or resistance exercises), acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), selected antidepressants and anticonvulsants (which have been shown to be effective for chronic pain) as recommended by the CDC.[394] The participant is only provided with the suggestion of prescribing more opioids. Not

[392] Id at 80.
[393] Id.
[394] CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. Morbidity and Mortality Weekly Report (MMWR). Recommendations and Reports / March 18, 2016 / 65(1);1–49. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm Errata. Vol. 65, No. RR-1. MMWR Morb Mortal Wkly Rep 2016;65:295. http://dx.doi.org/10.15585/mmwr.mm6511a6. (Accessed May 12, 2023).

surprising since several of the opioid manufacturers were intimately involved with the development of CO*RE Blueprint.

495. In 2016 the CDC provided a guideline which addresses "*1) when to initiate or **continue opioids for chronic pain**; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use*."[395] (Emphasis Added)

496. In this 2016 guideline, the CDC stated,

> "*When starting opioid therapy for **chronic pain**, clinicians should prescribe **immediate-release opioids*** (IR) *instead of extended-release/long-acting (ER/LA) opioids*. E*xercise therapy can help reduce pain and improve function in **chronic low back pain***.[396] (Emphasis Added).
>
> *"Several nonopioid pharmacologic therapies (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) are effective for chronic pain. In particular, acetaminophen and NSAIDs (nonsteroidal anti-inflammatory drugs) can be useful for arthritis and **low back pain***." (Emphasis Added)

497. In 2022, the CDC published an update to its 2016 recommendations.[397] This update "*provides recommendations for clinicians providing pain care, including those prescribing opioids, for outpatients aged ≥18 years*" Therein, the CDC advised that,

- "***Nonopioid therapies are at least as effective as opioids for many common acute pain conditions, including low back pain**, neck pain, pain related to other musculoskeletal injuries (e.g., sprains, strains, tendonitis, and bursitis), pain related to minor surgeries typically associated with minimal*

[395] CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. Morbidity and Mortality Weekly Report (MMWR). Recommendations and Reports / March 18, 2016 / 65(1);1–49. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm Errata. Vol. 65, No. RR-1. MMWR Morb Mortal Wkly Rep 2016;65:295. http://dx.doi.org/10.15585/mmwr.mm6511a6. (Accessed May 12, 2023).
[396] Id. at 5.

[397] CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. Morbidity and Mortality Weekly Report (MMWR). Recommendations and Reports / November 4, 2022 / 71(3);1–95. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1.htm_w. (Accessed May 12, 2023).

tissue injury and mild postoperative pain (e.g., simple dental extraction), dental pain, kidney stone pain, and headaches including episodic migraine. (Emphasis Added)

- *"**Noninvasive nonpharmacologic approaches should be used** as appropriate to alleviate acute pain, including ice and elevation to reduce swelling and discomfort from musculoskeletal injuries, heat to alleviate **low back pain**, and other modalities depending on the cause of the acute pain.* (Emphasis Added)
- *"**NSAIDs have been found to be more effective than opioids** for surgical dental pain and kidney stone pain and **similarly effective to opioids for low back pain** (ref).* (Emphasis Added).
- *"When not contraindicated, **NSAIDs should be used for low back pain**…"* (Emphasis Added).
- "*A systematic review*[398]*… found that opioids were **probably less effective than NSAIDs for surgical dental pain** and kidney stone pain, less effective than acetaminophen for kidney stone pain, and **similarly effective as NSAIDs for low back pain** (ref.).* (Emphasis Added).
- *"Clinicians should recommend appropriate **noninvasive nonpharmacologic approaches to help manage chronic pain**, such as exercise (e.g., aerobic, aquatic, or resistance exercises) or exercise therapy (a prominent modality in physical therapy) for **back pain.*** (Emphasis Added)
- "*When patients with **chronic low back pain** have had an insufficient response to nonpharmacologic approaches such as exercise, clinicians can consider NSAIDs or duloxetine for patients without contraindications.* (Emphasis Added).
- "*For **moderate to severe chronic back pain** or hip or knee osteoarthritis pain, a nonopioid strategy starting with acetaminophen or NSAIDs results*

[398] Busse JW, Sadeghirad B, Oparin Y, et al. Management of acute pain from non-low back, musculoskeletal injuries: a systematic review and network meta-analysis of randomized trials. Ann Intern Med 2020;173:730–8.

*in **improved pain intensity with fewer side effects compared with a strategy starting with opioids** (ref.).*"

- *"**High-quality evidence exists** that exercise therapy (a prominent modality in physical therapy) for **back pain**, fibromyalgia, and hip or knee osteoarthritis reduces pain and improves function immediately after treatment and that the improvements are sustained for at least 2–6 months (Refs).* (Emphasis Added)
- *"**No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain** with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤6 weeks in duration)* (Emphasis Added).
- ***"Extensive evidence shows the possible harms of opioids** (including opioid use disorder, overdose, and motor vehicle injury).* (Emphasis Added)
- ***"Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy**, with less harm.* (Emphasis Added)

498. The 2016 and 2022 guidelines and recommendations from the CDC are to be contrasted with that material presented by Medscape within the **ER/LA OPIOID REMS: Achieving Safe Use While Improving Patient Care** presentation - Presented by CO*RE Collaboration for REMS Education.[399]

499. CO*RE 'Staff Disclosures' revealed that Piyali Chatterjee, Director, Medical Education, **Medscape, LLC**, Cyndi Grimes, CCMEP, CME/CE Director, **Medscape, LLC**, and Sarah Williams, PhD, Scientific Director, **Medscape, LLC**, were part of the 'staff' developing this ER/LA OPIOID REMS.[400]

[399] ER/LA OPIOID REMS: Achieving Safe Use While Improving Patient Care. Presented by CO*RE Collaboration for REMS Education. (Slides 78-83). https://img.medscapestatic.com/images/841/340/841340_core_cd.pdf.
[400] Id.

500. Despite the 2016 and 2022 update by the CDC, the online program by Medscape and CO*RE, including opioid manufacturers, **only** advises the participants as to **which** dosages of oxycodone should be continued. **No mention of non-opioid therapy is offered even though the 2016 and 2022 CDC Guidelines recommend that**. Again, the not-so subtle undertone to this CME by Medscape and the opioid manufacturers is for the participants to just continue prescribing more opioids, **to the direct economic benefit to the opioid manufactures, the indirect benefit to Medscape and WebMD and to the detriment of Medicare, Medicaid, the VA Administration and other state and federal payees**. And, of course, ultimately, the U.S. taxpayer.

501. By May 30, 2018, RPC had funded 97.1% (866 of 892) of past, current, or planned ER/LA opioid REMS compliant activities; 93,192 active prescribers and more than 300,000 others successfully completed an activity by REMS CME providers[401]. **Internet activities accounted for more than 70% of participation**.[402] During 2018, 46,802 (69.5%) drug-related overdose deaths occurring in the U.S. involved an opioid.[403]

502. An '**Interim Analysis of Practice Changes Following Participation in Online and Live ER/LA Opioid REMS CME/CE Programs from the CO*RE Collaborative**' was presented at 'Pain Week 2016' in Las Vegas, NV in September 2016. Three of the five authors were employees of Medscape Education, LLC, and one author was the founder of Healthcare

[401] Goodwin B, Lim HD, Butler J, Paglia D, Dempsey MT, O Connor B, Fugh-Berman A. Increase your Confidence in Opioid Prescribing: Marketing Messages in Continuing Medical Education Activities on ER/LA Opioids. Pain Physician. 2021 Aug;24(5):E529-E538.

[402] Lembke A, Humphreys K, Newmark J. Weighing the risks and benefits of chronic opioid therapy. Am Fam Physician 2016; 93:982-990.

[403] Hedegaard H, Miniño AM, Warner M. Drug overdose deaths in the United States, 1999–2018. NCHS data brief, no 356. Hyattsville, MD: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2020. https://www.cdc.gov/nchs/data/databriefs/db356-h.pdf. (Accessed May 12, 2023).

Performance Consulting. The remaining author was a member of the California Academy of Family Physicians in San Francisco, CA, and the project lead for CO*RE.

503. This interim analysis

> "…*was designed to determine the effect of the first 30* ***CME/CE-certified RPC supported activities on planned and implemented changes involved in the safe and appropriate prescription of ER/LA opioid analgesics***."[404] (Emphasis Added).

504. Healthcare Performance Consulting utilized a process of Planned Change Assessment

> "…*to measure intended and completed changes in clinical practice following participation in educational programs. The PCA process allows for an immediate measure of program impact, as well as a delayed measure which more closely approximates actual behavior change.* ***It also allows the participants to be reminded of the program content, and their intent-to-change, at a point in time 1 to 6 months after the program***."[405]

505. This document also shows what general practice changes, for example, "*initiating, modifying, or discontinuing treatment with ER/LA opioid analgesics*," clinicians said they would make because of taking the CME program, and (as measured two months later) what changes a subset of these clinicians actually did make. This document omits the details (for example, whether there was an increase in off-label prescribing) but indicates that Healthcare Performance Consulting collected more specific data. Relator Elizabeth Saenger, PhD learned that collecting a particular kind of data post-program is standard for Healthcare Performance Consulting.

[404] https://img.medscapestatic.com/pi/edu/qrcode/posters/interim-analysis-of-practice-changes-opioid-rems-programs-core-collaborative.pdf (Accessed May 13, 2023).
[405] Id.

506. Medscape's **Pain Management and Opioids: Balancing Risks and Benefits-Updated 2019-20**[406] shows yet another false claim which could be expected to increase opioid prescriptions. It lists "Quality of life" as a benefit of taking opioids.

507. A 2018 study shows this to be yet another false claim.[407] The study compared the mental and physical health of matched chronic non-cancer pain patients in three groups: opioid users, non-opioid users, and non-chronic opioid users. Even with statistical controls in place to control for differences that might have led people to take opioids, there was no evidence that opioid users were better off. This study also noted that investigations found a better quality of life among those who did *not* take opioids, except for a few studies which found no difference between groups.

508. The research examined controlled for variables that might affect results by chance. For example, yet another study of low back pain patients found baseline opioid use was associated with higher disability six months after baseline, even with substantial statistical adjustments to remove possible confounds.[408]

509. In short, the RPC has commissioned CME with false claims about the safety, efficacy, and benefits of opioids. This material undermines the barriers clinicians have to prescribing opioids, and makes them less likely to choose treatments which are often safer, more effective, less expensive, and associated with a better quality of life.

510. These false claims include,[84]

- *"**Opioids are an appropriate treatment for chronic pain***".

[406] https://www.medscape.org/viewarticle/917714 (Accesses September 20, 2023)

[407] Hayes CJ, Li X, Li C, Shah A, Kathe N, Bhandari NR, Payakachat N. Health-Related Quality of Life among Chronic Opioid Users, Nonchronic Opioid Users, and Nonopioid Users with Chronic Noncancer Pain. Health Serv Res. 2018 Oct;53(5):3329-3349.

[408] Ashworth J, Green DJ, Dunn KM, Jordan KP. Opioid use among low back pain patients in primary care: Is opioid prescription associated with disability at 6-month follow-up? Pain. 2013 Jul;154(7):1038-44.

504. Opioids are not the most effective treatment for long-term, non-cancer pain. In fact, in 2018, the U.S. Department of Veterans Affairs, in its **Safe and Responsible Use of Opioids for Chronic Pain - A Patient Information Guide**, stated that opioids are no longer recommended for the treatment of most patients with chronic pain.[409] The use of opioids for the management of acute low back pain and neck pain is not supported by direct and robust evidence.[410-411]

- **"*ER/LAs [Extended Release/Long-Acting] are more appropriate than immediate-release (IR) opioids for chronic pain*".**

505. In fact, in its 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, the CDC advised that "*There is no evidence that ER/LA opioids are more effective or safer than IR opioids, and* ***there is a higher overdose risk when initiating treatment with ER/LA*** *opioids as compared to IR opioids*." (Emphasis added).

- **"*Tolerance is normal, expected, and beneficial*".**

506. One reason opioid addiction is so common is that people who develop tolerance may feel driven to increase their doses so they can keep feeling good.[412]

- **"*There is no population for whom opioids are absolutely contraindicated or inappropriate*."**

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[409] Safe and Responsible Use of Opioids for Chronic Pain - A Patient Information Guide. U.S. Department of Veterans Affairs. October 2018. https://www.va.gov/PAINMANAGEMENT/Opioid_Safety/OSI_docs/10791Safe_and_Responsible_Use_508.pdf (Accessed May 12, 2023).

[410] Deyo RA, Von Korff M, Duhrkoop D. Opioids for low back pain. BMJ. 2015 Jan 5;350:g6380.

[411] Jones CMP, Day RO, Koes BW, et al., OPAL Investigators Coordinators. Opioid analgesia for acute low back pain and neck pain (the OPAL trial): a randomised placebo-controlled trial. Lancet. 2023 Jun 27:S0140-6736(23)00404-X.

[412] How Opioid Addiction Occurs. The Mayo Clinic. https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/in-depth/how-opioid-addiction-occurs/art-20360372. (Accessed May 12, 2023).

507. Opioid therapy trial should NOT be initiated if any of the following absolute contraindications are evident[413]:

i. Severe respiratory instability.

ii. Acute psychiatric instability or uncontrolled suicide risk.

iii. Diagnosed substance use disorder not in remission or under treatment.

iv. A history of substance abuse.

v. Drug diversion.

- **"Screening and monitoring tools are effective for preventing opioid-related problems."**

508. Moore et al.[414] reported that *"[s]elf-report* ***was no better than chance*** *in predicting those who would have an opioid aberrant behavior*" and they concluded that *"[t]he self-report ORT [Opioid Risk Tool] was* ***not a valid test*** *for the prediction of future aberrant behaviors in this academic pain management population*."

- **"*Opioid related adverse effects, such as respiratory depression and addiction, are due only to misuse and abuse*."**

509. In fact, opioids used exactly as prescribed and without concomitant medications can cause addiction, respiratory depression, and death.[415,416,417] For seniors, long-term use of prescription opioids also increases the likelihood of falls and fractures.[418]

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[413] United States Department of Veterans Affairs. Opioid Initiation. https://www.va.gov/painmanagement/docs/opioid_initiation_note.docx. (Accessed May 13, 2023).

[414] Moore TM, Jones T, Browder JH, Daffron S, Passik SD. A comparison of common screening methods for predicting aberrant drug-related behavior among patients receiving opioids for chronic pain management. Pain Med. 2009 Nov;10(8):1426-33.

[415] Lembke A, Humphreys K, Newmark J. Weighing the risks and benefits of chronic opioid therapy. Am Fam Physician 2016; 93:982-990.

[416] Chau, Diane L. et al. "Opiates and Elderly: Use and Side Effects." Clinical Interventions in Aging, 2008, p. 276. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2546472/ on May 13, 2023. A

[417] CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016. MMWR Recomm Rep, March 18, 2016.

[418] Saunders, Kathleen W. et al. "Relationship of Opioid Use and Dosage Levels to Fractures in Older Chronic Pain Patients." Journal of General Internal Medicine, 2010, pp. 310–15. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842546/ on May 13, 2023.

- **"*Addiction, overdose, and death are due to street drugs such as heroin and fentanyl, not prescription opioids*."**

510. Not true! Drug overdose deaths involving prescription opioids rose from 3,442 in 1999 to 17,029 in 2017.[419] A 2021 analysis by Goodwin et al., of all internet-based REMS CME activities funded by the REMS consortium of ER/LA opioid manufacturers was performed to,

> "*…determine whether industry-funded REMS on long-acting opioids were consistent with the FDA's goal to reduce serious, adverse outcomes resulting from inappropriate prescribing, misuse, and abuse*."[84]

511. Goodwin et al. concluded that "*[i]ndustry-funded REMS-compliant CME on opioids* ***contain messages that misrepresent scientific evidence and may foster overprescribing of opioids***."[84] (Emphasis added).

512. CO*RE originally aimed to educate 650,000 healthcare providers about opioids. As of today, it has reached:

- more than 750,000 physicians, nurse practitioners and physician assistants who prescribe opioids;
- other healthcare professionals who influence healthcare and counsel patients
- healthcare in hospitals, birthing centers, palliative hospice, chronic pain clinics, and emergency departments and the millions of patients cared for by CO*RE's clinician members and learners.[420]

513. Unfortunately, the messages CO*RE, HPC, and the RPC broadcast contradict the research described in the peer-reviewed literature. More tellingly, these messages challenge the facts in their own Needs Assessment, leading to CE which propagates false and misleading claims.

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[419] Drug Overdose Death Rates. National Institute on Drug Abuse. https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates. (Accessed May 13, 2023).
[420] "Our Reach" at https://core-rems.org/about-core/

514. Except as alleged herein, the facts concerning Defendants' violations of the False Claims Act are exclusively within their custody and control, and not available to the Qui Tam Plaintiff. Defendants concealed their conspiracy to the detriment of the Government Healthcare Programs.

FIRST CAUSE OF ACTION

VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT 31 U.S.C. §§ 3729

468. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

469. The False Claims Act ("FCA"), 31 U.S.C. §3729 (a)(l) and (2), imposes liability upon those who knowingly present, or cause to be presented, false claims for payment or approval of payment to an officer or employee of the United States, and on those who conspire to cause false claims to be paid or approved. 31 U.S.C. §3729 (a)(3).

470. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

471. By virtue of the acts described above, Defendants knowingly conspired and colluded amongst themselves and with various pharmaceutical companies to present the products of those companies in biased, false, misleading, untruthful, and off-label manners to encourage the prescribing of said pharmaceutical products which has led to and continues to lead to fraudulent claims made to the United States Government including the aforementioned 'Government Healthcare Programs'.

472. By virtue of the acts described above, the Defendants knowingly aided, abetted, colluded, and conspired, made, or used, or caused to be made or used, false, or fraudulent records or statements material to false or fraudulent claims for payment by the Government.

473. Relator cannot at this time identify all the false claims for payment that were caused by Defendants' conduct. The false claims were presented by several separate entities.

474. The Relator does not have access to the records of all such false or fraudulent statements, records, or claims.

475. The Government, unaware of the falsity of the records, statements, and claims made or caused because of the collusion and conspiracy between the Defendants and the involved pharmaceutical manufacturers, paid and continues to pay the claims that would not be paid but for Defendant' illegal conduct.

476. Due to Defendants' conduct, the Government has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. 31 U.S.C. § 3729. 156.

477. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

478. Relator is entitled to a reasonable attorney's fees and costs, pursuant to 31 U.S.C. § 3730(d)(1).

SECOND CAUSE OF ACTION

CONSPIRACY TO VIOLATE THE FALSE CLAIMS ACT, TO UNLAWFULLY PROMOTE OFF-LABEL, MISLEADINGLY, UNTRUTHFULLY AND/OR FALSELY VARIOUS PHARMACEUTICAL COMPANIES' PHARMACEUTICAL PRODUCTS. 32 U.S.C Section (a)(1)(C)

UNITED STATES OF AMERICA V. ALL DEFENDANTS

THE CONSPIRACY

479. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

480. From at least 2004 up to and including the present, Medscape, WebMD, CE Outcomes, Healthcare Performance Consulting, and Healthcare Internet Brands unlawfully, willfully and knowingly did aid, abet, combine, conspire, confederate and agree together to present and promote the off-label, misleading, untruthful and false representations and indications for various pharmaceutical companies' pharmaceutical agents which resulted and results in those said pharmaceutical companies presenting increased numbers of prescriptions of their pharmaceutical agents to the aforementioned 'Government Healthcare Programs'. As a direct and proximate result of this collusion and conspiracy between the defendants and various pharmaceutical companies, said pharmaceutical companies pay WebMD, through Medscape, for the off label, unlawful, misleading, and false presentation, and promotion, of said pharmaceutical companies' drugs unlawfully, to defraud the United States in violation of 31 U.S.C. §3729 (a)(1-3) and the above-named Plaintiff-States in violation of their respective State FCAs.

481. As alleged herein, the Defendants frequently knew that information contained within the presentations which their pharmaceutical clients paid for, sponsored, and/or presented, was false and would lead to increased prescribing of the pharmaceutical clients' products to the detriment of the federal and states' healthcare programs and, by extension, the U.S. taxpayers. As a result of the Defendants' conduct, the federal and state governments described herein have suffered substantial monetary damages and are entitled to recover treble damages and a civil penalty for each false claim, record, or statement. 31 U.S.C. § 3729. 156.

482. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

483. Relator is entitled to a reasonable attorney's fees and costs, pursuant to 31 U.S.C. § 3730(d)(1).

THIRD CAUSE OF ACTION

VIOLATION OF ANTI-KICKBACK STATUTE 42 U.S. CODE § 320a–7b(b)

484. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

485. From at least 2004 up to and including the present, Medscape, WebMD, CE Outcomes, Healthcare Performance Consulting, and Healthcare Internet Brands unlawfully, willfully, and knowingly did solicited and received value in the form of fees to induce and/or generate continuing medical education programs designed to promote pharmaceutical companies' drugs in an off-label, false, misleading and/or untruthful manner.

486. Under the federal Anti-Kickback Statute, a company commits fraud when it offers financial incentives to use or promote the company's products or services, for which payment may be made under Medicare, Medicaid, or other federally funded healthcare programs. The Department of Health and Human Services Office of the Inspector General ('HHS-OIG') Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (1991) are unambiguous in offering a broad definition of the term "remuneration" as "anything of value in any form whatsoever".

487. As a direct and proximate result of this collusion and conspiracy among the defendants and various pharmaceutical companies, said pharmaceutical companies pay WebMD, through Medscape, for the off-label, unlawful, misleading, and false presentation, and promotion, of said pharmaceutical companies' drugs unlawfully, to defraud the United States and the named States herein in violation of the Anti-Kickback Statute 42 U.S. CODE § 320a–7b(b) and Ala. Code

§ 22-1-11(b)-(c); Alaska Stat. Ann. § 11.46.660(a)(3); Ariz. Rev. Stat. Ann. 13-3713(A), Ark. Code Ann. § 20-77-902(6)-(7), Cal. Welf. & Inst. Code § 14107.2, Colo. Rev. Stat. § 24-31-809, Conn. Gen. Stat. § 53a-161c(a)(2), Del. Code. Ann. Tit. 31, § 1005, D.C. Code § 4-802(c)-(d), Fla. Stat. § 456.054(2)-(3), Ga. Code Ann. § 43-1B-4(7), Haw. Rev. Stat. Ann. § 431:10C308.7(b)-(c), Idaho Code Ann. § 41-348(1), 305 Ill. Comp. Stat. 5/8A, Ind. Code Ann. § 12-15-24-2, Iowa Admin. Code r. 653-13.7(147,148,272c)(2), Kan. Stat. Ann. § 21-5928(a)(1)-(2), Ky. Rev. Stat. Ann. § 216.2950(1)-(2), La. Rev. Stat. Ann. § 46:438.2, Md. Code Ann., Crim. Law § 8-511, Mass. Gen. Laws ch. 118E, § 41, Mich. Comp. Laws § 400.604, Minn. Stat. Ann. § 147.091(1)(p)(1), Miss. Code Ann § 43-13-207, Mo. Rev. Stat. § 191.905(2)-(3), Mont. Code Ann. § 45-6-313(1)(b), Nev. Rev. Stat. § 422.560, N.H. Rev. Stat. Ann. § 167:61-a(I)(i), N.J. Stat. Ann. § 2C:21-10(a)(3), (c), N.M. Stat. Ann. § 30-44-7(A)(1), N.Y. Soc. Serv. Law § 366-d, N.C. Gen Stat. § 90-401, N.D. Cent. Code Ann. § 50-24.8-11(1), Ohio Rev. Code Ann. § 2913.40(C)(2), Okla. Stat. Ann. tit. 56, § 1005(A)(6), Ore. Admin. R. 410-120-1400(4)(a), 62 Pa. Stat. § 1407(a)(2), R.I. Gen. Laws § 40-8.2-3(a)(2), S.C. Code Ann. § 44-113-60, S.D. Codified Laws § 22-45-4(3), Tenn. Code Ann. § 63-6-225(b), Texas Occ. Code Ann. § 102.001(a), Utah Code Ann. § 26-20-4, Vt. Stat. Ann. tit. 26, § 1354(12), Va. Code Ann. § 32.1-315, Wash. Rev. Code Ann. § 74.09.240(1)-(2), W. Va. Code § 9-7-5(a), Wis. Stat. Ann. § 448.08.

488. When successful, the Relator will receive between 15 and 30 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

FOURTH CAUSE OF ACTION

VIOLATION OF CALIFORNIA GOVERNMENT CODE SECTION 12651 - CALIFORNIA FALSE CLAIMS ACT

489. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

490. As set forth above, Defendants knowingly colluded and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in fraudulent claims made to the California Medicaid program, in violation of Cal. Gov't Code § 12651(a)(1).

491. As set forth above, Defendants knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Cal. Gov't Code § 12651(a)(2).

492. Due to Defendants' conduct, the State of California has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Cal. Gov't Code § 12651(a).

493. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

494. Relator is entitled to reasonable attorneys' fees, costs, and expenses. Cal. Gov't Code § 12652(g). All such expenses, fees, and costs shall be awarded against the defendants.

FIFTH CAUSE OF ACTION

VIOLATIONS OF THE COLORADO FALSE CLAIMS ACT AND COLORADO MEDICAID FALSE CLAIMS ACT COLO. REV. STAT. ANN. § 24-31-101 *et seq.* & COLO. REV. STAT. § 25.5-4-303.5

495. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

496. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in fraudulent claims made to the Colorado Medicaid program false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(1)(a) and Colo. Rev. Stat. Ann. § 24-31-101 et seq.

497. Due to Defendants' conduct, the State of Colorado has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Colo. Rev. Stat. § 25.5-4-305(1). A person who makes a false claim is liable to the state for a civil penalty of $11,800 to $23,600 per violation, plus 3 times the amount of the damages sustained by the state.

498. If the state proceeds with this action brought by Relator under subsection (2) of Colo. Rev. Stat. § 25.5-4-306, the Relator shall, subject to subparagraph (II) of paragraph (a), receive at least fifteen percent but not more than twenty-five percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the relator substantially contributed to the prosecution of the action.

499. If the court finds the action to be based primarily on disclosures of specific information, other than information provided by the relator, relating to allegations or transactions in a criminal, civil, or administrative hearing, in a legislative, administrative, or state auditor's report, hearing, audit, or investigation, or from the news media, the court may award to the relator such sums as it considers appropriate, but in no case more than ten percent of the proceeds, taking into acCAUSE OF ACTION the significance of the information and the role of the relator in advancing the case to litigation.

500. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

501. Relator is entitled to reasonable attorney's fees, costs, and expenses. Colo. Rev. Stat. § 25.5-4-306(4). All such expenses, fees, and costs shall be awarded against the defendants.

SIXTH CAUSE OF ACTION

VIOLATIONS OF CONNECTICUT GENERAL STATUTES § 4-274 et seq. – CONNECTICUT FALSE CLAIMS ACT FOR MEDICAL ASSISTANCE PROGRAMS

502. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

503. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to the Connecticut Medicaid in violation of Conn. Gen. Stat. § 4-275(a)(1).

504. The Connecticut False Claims Act follows the Federal False Claims Act in most important respects. Specifically, the Connecticut Law creates liability for presenting false claims, for creating false records to obtain payment, and for conspiracy to violate the act. It provides similar liability as the federal law by imposing treble damages on defendants who violate the act. In addition, the law also imposes civil fines of $5,500 to $11,000 per violation.

505. Individuals who sue under this law can obtain between 15 and 30 percent of whatever the government recovers as a result of the action filed. In a case pursued by the Connecticut Attorney General, the whistleblower may receive between 15 and 25 percent of the total recovery.

506. Due to Defendant's conduct, the State of Connecticut has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Conn. Gen. Stat. § 4-275(a).

507. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

508. Relator is entitled to reasonable attorneys' fees, costs, and expenses. Conn. Gen. Stat. § 4-278. All such expenses, fees, and costs shall be awarded against the defendants.

SEVENTH CAUSE OF ACTION

VIOLATIONS OF DELAWARE CODE TITLE 6, § 12-1201 - DELAWARE FALSE CLAIMS AND REPORTING ACT

509. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

510. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Delaware Medicaid program false or fraudulent claims for payment or approval, in violation of Del. Code Tit. 6, § 12-1201(a)(1).

511. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Del. Code Tit. 6, § 12-1201(a)(2).

512. Due to Defendant's conduct, the State of Delaware has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Del. Code Tit. 6, § 12-1201(a).

513. If the Department of Justice proceeds with an action brought by a party under §1203(b), such party shall receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the party substantially contributed to the prosecution of the action.

514. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

515. Relator is entitled to reasonable attorney's fees, costs, and expenses pursuant to Del. Code Tit. 6, § 12-1205. All such expenses, fees, and costs shall be awarded against the defendants.

EIGHTH CAUSE OF ACTION

VIOLATIONS OF DISTRICT OF COLUMBIA CODE § 2-308.02 DISTRICT OF COLUMBIA FALSE CLAIMS ACT

516. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

517. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the District of Columbia Medicaid program false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-308.02(a)(1).

518. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of D.C. Code § 2-308.02(a)(2).

519. Due to Defendants' conduct, the District of Columbia has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. D.C. Code § 2-308.14(a).

520. The District of Columbia False Claims Act states that, when the government intervenes in an action, the Relator is entitled to receive between fifteen percent (15%) and twenty five percent (25%) of the proceeds of that action, "*depending upon the extent to which the person substantially contributed to the prosecution of the action*."

521. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

522. The Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to D.C. Code § 2-381.03(f). All such expenses, fees, and costs shall be awarded against the defendants.

NINTH CAUSE OF ACTION

VIOLATIONS OF FLORIDA STATUTE § 68.082 FLORIDA FALSE CLAIMS ACT

523. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

524. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Florida Medicaid program for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

525. As set forth above, Defendants knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Fla. Stat. § 68.082(2)(b).

526. Due to Defendants' conduct, the State of Florida has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Fla. Stat. § 68.082(2).

527. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

528. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Fla. Stat. § 68.085. All such expenses, fees, and costs shall be awarded against the defendants.

TENTH CAUSE OF ACTION

VIOLATIONS OF GEORGIA FALSE MEDICAID CLAIMS ACT O.C.G.A. § 49-4-168.1

529. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

530. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Georgia Medicaid program in violation of O.C.G.A. § 49-4-168.1(a)(1).

531. As set forth above, Defendants knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of O.C.G.A. § 49-4-168.1(a)(2).

532. Due to Defendants' conduct, the State of Georgia has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. O.C.G.A. § 49-4-168.1.

533. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

534. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to O.C.G.A. § 49-4-168.2(i). All such expenses, fees, and costs shall be awarded against the defendants.

ELEVENTH CAUSE OF ACTION

VIOLATIONS OF HAWAII REVISED STATUTES § 661-21 HAWAII FALSE CLAIMS ACT

535. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

536. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Hawaii Medicaid program false or fraudulent claims for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(1).

537. As set forth above, Defendants knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Haw. Rev. Stat. § 661-21(a)(2).

538. Due to Defendant's conduct, the State of Hawaii has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Haw. Rev. Stat. § 661-21(a).

539. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

540. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Haw. Rev. Stat. § 661-27. All such expenses, fees, and costs shall be awarded against the defendants.

TWELFTH CAUSE OF ACTION

VIOLATIONS OF 740 ILLINOIS COMPILED STATUTES § 175/3 ILLINOIS FALSE CLAIMS ACT

541. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

542. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Illinois Medicaid program false or fraudulent claims for payment or approval, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1)(A).

543. As set forth above, Defendants knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Ill. Comp. Stat. § 175/3(a)(1)(B).

544. Due to Defendants' conduct, the State of Illinois has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Ill. Comp. Stat. § 175/3(a)(1).

545. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

546. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Ill. Comp. Stat. § 175/4(d)(1). All such expenses, fees, and costs shall be awarded against the defendants.

THIRTEENTH CAUSE OF ACTION

VIOLATIONS OF INDIANA CODE § 5-11-5.5-2 INDIANA MEDICAID FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

547. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

548. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Indiana Medicaid program false or fraudulent claims for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(1).

549. Due to Defendants' conduct, the State of Indiana has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Ind. Code § 5-11-5.5-2(b).

550. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

551. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Ind. Code § 5-11-5.5-6(a). All such expenses, fees, and costs shall be awarded against the defendants.

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FOURTEENTH CAUSE OF ACTION

VIOLATIONS OF IOWA CODE § 685 – IOWA FALSE CLAIMS ACT

552. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

553. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Iowa Medicaid program false or fraudulent claims for payment or approval, in violation of Iowa Code § 685.2(1)(a).

554. As set forth above, Defendants knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Iowa Code § 685.2(1)(b).

555. Due to Defendant's conduct, the State of Iowa has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Iowa Code § 685.2(1).

556. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

557. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Iowa Code § 685.3(4)(a). All such expenses, fees, and costs shall be awarded against the defendants.

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FIFTEENTH CAUSE OF ACTION

VIOLATIONS OF LOUISIANA REVISED STATUTES ANNOTATED § 46:438.3 MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

558. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

559. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Louisiana Medical Assistance Program in violation of La. Rev. Stat. Ann. § 46:438.3(A).

560. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of La. Rev. Stat. Ann. § 46:438.3(B).

561. Due to Defendant's conduct, the State of Louisiana has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. La. Rev. Stat. Ann. § 46:438.6.

562. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

563. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to La. Rev. Stat. Ann. § 46:438.6(D). All such expenses, fees, and costs shall be awarded against the defendants.

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SIXTEENTH CAUSE OF ACTION

VIOLATIONS OF MARYLAND CODE ANNOTATED § 2-602 MARYLAND FALSE HEALTH CLAIMS ACT

564. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

565. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Maryland Medicaid program false or fraudulent claims for payment or approval, in violation of Md. Code Ann. § 2-602(a)(1).

566. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Md. Code Ann. § 2-602(a)(2).

567. As set forth above, Defendant knowingly made other false or fraudulent claims against a State health plan or a State health program, in violation of Md. Code Ann. § 2-602(a)(9).

568. Due to Defendant's conduct, the State of Maryland has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Md. Code Ann. § 2-602(b)(1).

569. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

570. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Md. Code Ann. § 2-603(b)(2)(ii) and § 2-605(a). All such expenses, fees, and costs shall be awarded against the defendants.

SEVENTEENTH CAUSE OF ACTION

VIOLATIONS OF MASSACHUSETTS GENERAL LAW Ch. 12, § 5 – MASSACHUSETTS FALSE CLAIMS ACT

571. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

572. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Massachusetts Medicaid program false or fraudulent claims for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(a)(1).

573. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies causing to be made, used, or caused to be

made or used, false records or statements material to false claims, in violation of Mass. Gen. Laws ch. 12 § 5B(a)(2).

574. Due to Defendant's conduct, the State of Massachusetts has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Mass. Gen. Laws ch. 12 § 5B(a).

575. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

576. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Mass. Gen. Laws ch. 12 § 5F. All such expenses, fees, and costs shall be awarded against the defendants.

EIGHTEENTH CAUSE OF ACTION

VIOLATIONS OF MICHIGAN COMPILED LAWS 400.601 et seq.
MICHIGAN MEDICAID FALSE CLAIMS ACT

577. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

578. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Michigan Medicaid program false or fraudulent claims for payment or approval, in violation of Mich. Comp. Laws 400.607.

579. As set forth above, Defendants conspired to commit a violation of the Michigan Medicaid False Claims Act, in violation of Mich. Comp. Laws 400.606.

580. Due to Defendant's conduct, the State of Michigan has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Mich. Comp. Laws 400.612(1), an amount that will be proven at trial.

581. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

582. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Mich. Comp. Laws 400.610a(9). All such expenses, fees, and costs shall be awarded against the defendants.

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NINETEENTH CAUSE OF ACTION

VIOLATIONS OF MINNESOTA STATUTE § 15C.02
MINNESOTA FALSE CLAIMS ACT

583. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

584. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Minnesota Medicaid program false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

585. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with various pharmaceutical companies resulting in made, used, or caused to be made or used, false records or statements material to false claims, in violation of Minn. Stat. § 15C.02(a)(2).

586. Due to Defendants' conduct, the State of Minnesota has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Minn. Stat. § 15C.02(a).

587. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

588. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Minn. Stat. § 15C.12. All such expenses, fees, and costs shall be awarded against the defendants.

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TWENTIETH CAUSE OF ACTION

VIOLATIONS OF MONTANA CODE ANNOTATED § 17-8-401 MONTANA FALSE CLAIMS ACT

589. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

590. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Montana Medicaid program false or fraudulent claims for payment or approval, in violation of Mont. Code Ann. § 17-8-403(1)(a).

591. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with various pharmaceutical companies resulting in made, used, or caused to be made or used, false records or statements material to false claims, in violation of Mont. Code Ann. § 17-8-403(1)(b).

592. Due to Defendants' conduct, the State of Montana has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Mont. Code Ann. § 17-8-403(1).

593. A successful whistleblower will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene a successful whistleblower will receive between 25 and 30 percent of the proceeds.

594. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Mont. Code Ann. § 17-8-410(3). All such expenses, fees, and costs shall be awarded against the defendants.

TWENTY FIRST CAUSE OF ACTION

VIOLATIONS OF NEVADA REVISED STATUTE ANNOTATED § 357.040 SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT

595. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

596. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Nevada Medicaid program false or fraudulent claims for payment or approval, in violation of Nev. Rev. Stat. Ann. § 357.040(1)(a).

597. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with various pharmaceutical companies resulting in made, used, or caused to be made or used, false records or statements material to false claims, in violation of Nev. Rev. Stat. Ann. § 357.040(1)(b).

598. Due to Defendant's conduct, the State of Nevada has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Nev. Rev. Stat. Ann. § 357.040(2).

599. A successful whistleblower will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene a successful whistleblower will receive between 25 and 30 percent of the proceeds.

600. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Nev. Rev. Stat. Ann. § 357.180. All such expenses, fees, and costs shall be awarded against the defendants.

TWENTY SECOND CAUSE OF ACTION

NEW HAMPSHIRE REVISED STATUTES
TITLE XII - PUBLIC SAFETY AND WELFARE
CHAPTER 167 - SECTION 167:61-B
FALSE CLAIMS AGAINST THE DEPARTMENT

601. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

602. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to an employee, officer or agent of the State, or to any contractor, grantee,

or other recipient of State funds, a false or fraudulent claim for payment or approval, in violation of the New Hampshire Medicaid program. Section 167:61-B.

603. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with various pharmaceutical companies resulting in made, used, or caused to be made or used, false records or statements material to false claims, in violation of the New Hampshire Medicaid program.

604. Due to Defendants' conduct, the State of New Hampshire has suffered substantial monetary damages and is entitled to recover from any person liable to the state a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages that the state sustains because of the act of that person who conspires to defraud the department by getting a false or fraudulent claim allowed or paid.

605. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

606. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to N.H. Rev. Stat. Ann. §§ 167:61-167:61-e. All such expenses, fees, and costs shall be awarded against the defendants.

TWENTY THIRD CAUSE OF ACTION

VIOLATIONS OF NEW JERSEY REVISED STATUTE § 2A:32C-3 NEW JERSEY FALSE CLAIMS ACT

607. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

608. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said

companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval, in violation of N.J. Rev. Stat. § 2A:32C-3(a).

609. Due to Defendants' conduct, the State of New Jersey has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. N.J. Rev. Stat. § 2A:32C-3.

610. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

611. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to N.J. Rev. Stat. § 2A:32C-8. All such expenses, fees, and costs shall be awarded against the defendants.

TWENTY FOURTH CAUSE OF ACTION

VIOLATIONS OF NEW MEXICO STATUTE § 27-14-2
NEW MEXICO MEDICAID FALSE CLAIMS ACT

612. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

613. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the New Mexico Medicaid program false or fraudulent claims for payment or approval, in violation of N.M. Stat. § 27-14-4(A).

614. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with various pharmaceutical companies resulting in made, used, or caused to be made or used, false records or statements material to false claims, in violation of knowingly presented or caused to be presented to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program, in violation of N.M. Stat. § 27- 14-4(B).

615. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with various pharmaceutical companies resulting in made, used, or caused to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false, in violation of N.M. Stat. § 27-14-4(C).

616. Due to Defendant's conduct, the State of New Mexico has suffered substantial monetary damages and is entitled to recover treble damages. N.M. Stat. § 27-14-4.

617. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

618. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to N.M. Stat. § 27-14-9. All such expenses, fees, and costs shall be awarded against the defendants.

TWENTY FIFTH CAUSE OF ACTION

VIOLATIONS OF NEW YORK UNIFORM COMMERCIAL CODE LAW § 189 NEW YORK FALSE CLAIMS ACT

619. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

620. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval, in violation of N.Y. U.C.C. Law § 189(1)(a).

621. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made, used, or caused to be made or used, false records or statements material to false claims, in violation of N.Y. U.C.C. Law § 189(1)(b).

622. Due to Defendant's conduct, the State of New York has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. N.Y. U.C.C. Law § 189(1).

623. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

624. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to N.Y. U.C.C. Law § 190(6). All such expenses, fees, and costs shall be awarded against the defendants.

TWENTY SIXTH CAUSE OF ACTION

VIOLATIONS OF NORTH CAROLINA GENERAL STATUTE § 1-607 NORTH CAROLINA FALSE CLAIMS ACT

625. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

626. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).

627. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

628. Due to Defendants' conduct, the State of North Carolina has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. N.C. Gen. Stat. § 1-607(a).

629. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

630. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to N.C. Gen. Stat. § 1-610. All such expenses, fees, and costs shall be awarded against the defendants.

TWENTY SEVENTH CAUSE OF ACTION

VIOLATIONS OF OKLAHOMA STATUTE TITLE 63, § 5053.1 OKLAHOMA MEDICAID FALSE CLAIMS ACT

631. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

632. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Oklahoma Medicaid program false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

633. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made, used, or caused to be made or used, false records or statements to get a false or fraudulent claim paid or approved by the state, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).

634. Due to Defendants' conduct, the State of Oklahoma has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Okla. Stat. tit. 63, § 5053.1(B).

635. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

636. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Okla. Stat. tit. 63, § 5053.4. All such expenses, fees, and costs shall be awarded against the defendants.

TWENTY EIGHTH CAUSE OF ACTION

THE FRAUDULENT CLAIMS TO PROGRAMS, CONTRACTS, AND SERVICES OF THE GOVERNMENT OF PUERTO RICO ACT.

637. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

638. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval, in violation of the Fraudulent Claims to Programs, Contracts, and Services of the Government of Puerto Rico Act.

639. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of the Fraudulent Claims to Programs, Contracts, and Services of the Government of Puerto Rico Act.

640. Due to Defendants' conduct, the Commonwealth of Puerto Rico has suffered substantial monetary damages and is entitled to recover damages and a criminal and civil penalty for each false claim, record, or statement.

641. "*Any person who conspires with another to defraud the Government and commits a violation of any of the provisions of this Act in order to obtain or cause another to obtain an unauthorized payment or benefit under the Medicaid Program shall be guilty of a felony and punished by imprisonment for a fixed term of three (3) years. If there are aggravating*

circumstances, the fixed punishment may be increased to up to five (5) years; if there are mitigating circumstances, the punishment may be reduced to a minimum of two (2) years."

642. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

643. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to the Fraudulent Claims to Programs, Contracts, and Services of the Government of Puerto Rico Act. All such expenses, fees, and costs shall be awarded against the defendants.

TWENTY NINETH CAUSE OF ACTION

VIOLATIONS OF RHODE ISLAND GENERAL LAWS § 9-1.1-3 RHODE ISLAND FALSE CLAIMS ACT

644. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

645. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Rhode Island Medicaid program false or fraudulent claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

646. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of the R.I. Gen. Laws § 9-1.1-3(a)(2).

647. Due to Defendants' conduct, the State of Rhode Island has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. R.I. Gen. Laws § 9-1.1-3(a).

648. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

649. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to R.I. Gen. Laws § 9-1.1-4(d). All such expenses, fees, and costs shall be awarded against the defendants.

THIRTIETH CAUSE OF ACTION

VIOLATIONS OF TENNESSEE CODE ANNOTATED § 71-5-182 TENNESSEE MEDICAID FALSE CLAIMS ACT

650. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

651. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Tennessee Medicaid program false or fraudulent claims for payment or approval, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

652. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of the Tenn. Code Ann. § 71-5-182(a)(1)(B).

653. Due to Defendants' conduct, the State of Tennessee has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Tenn. Code Ann. § 71-5-182(a).

654. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

655. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Tenn. Code Ann. § 71-5-183(d). All such expenses, fees, and costs shall be awarded against the defendants.

THIRTY FIRST CAUSE OF ACTION

VIOLATIONS OF TEXAS CODE § 36.002
TEXAS MEDICAID FRAUD PREVENTION ACT

656. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

657. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized, in violation of Tex. Code § 36.002(1).

658. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or misrepresentation of a material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program, in violation of Tex. Code § 36.002(4)(B).

659. As set forth above, Defendants knowingly or intentionally aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in said pharmaceutical companies charged, solicited, accepted, or received, in addition to an amount paid under the Medicaid program, a gift, money, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient where the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program, in violation of Tex. Code § 36.002(5).

660. As set forth above, Defendants knowingly engaged in conduct that constitutes a violation of Tex. Code § 32.039(b), thus also violating Tex. Code. § 36.002(13).

661. The State of Texas is entitled to three times the amount of any payment or the value of any monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, because of the unlawful act, including any payment made to a third party. Tex. Code §§ 36.052(a)(1) and 36.052(a)(4).

662. The State of Texas is entitled to prejudgment interest on the amount of the payment or the value of the benefit described in the above paragraph at the prejudgment interest rate in effect on the day the payment or benefit was received or paid, for the period from the date the benefit was received or paid to the date that the state recovers the amount of the payment or value of the benefit.

663. The State of Texas is entitled to a civil penalty as required by Tex. Code § 36.052(a)(3)(B) for each unlawful act committed by Defendants.

664. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

665. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Tex. Code § 36.110. All such expenses, fees, and costs shall be awarded against the defendants.

THIRTY SECOND CAUSE OF ACTION

VIOLATIONS OF VERMONT STATUTE ANNOTATED § 631 VERMONT FALSE CLAIMS ACT

666. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

667. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Vermont Medicaid program false or fraudulent claims for payment or approval, in violation of Vt. Stat. Ann. § 631(a)(1).

668. As set forth above, Defendants knowingly aided, abetted, colluded, and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims presented or caused to be presented to the Vermont Medicaid program false or fraudulent claims for payment or approval, in violation of Vt. Stat. Ann. § 631(a)(2).

669. Due to Defendants' conduct, the State of Vermont has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Vt. Stat. Ann. § 631(b).

670. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

671. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Vt. Stat. Ann. § 635(c). All such expenses, fees, and costs shall be awarded against the defendants.

THIRTY THIRD CAUSE OF ACTION

VIOLATIONS OF VIRGINIA CODE ANNOTATED § 8.01-216.3 VIRGINIA FRAUD AGAINST TAXPAYERS ACT

672. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

673. As set forth above, Defendants knowingly colluded and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Virginia Medicaid program false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

674. Defendants knowingly colluded and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products and resulting in false records or statements material to false claims, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

675. Due to Defendants' conduct, the State of Virginia has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Va. Code Ann. § 8.01-216.3(A).

676. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

677. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Va. Code Ann. § 8.01-216.7. All such expenses, fees, and costs shall be awarded against the defendants.

THIRTY FOURTH CAUSE OF ACTION

VIOLATIONS OF WASHINGTON REVISED CODE § 74.66.020 WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT

678. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

679. As set forth above, Defendants knowingly colluded and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Washington Medicaid program false or fraudulent claims for payment or approval, in violation of Wash. Rev. Code § 74.66.020(1)(a).

680. Defendants knowingly colluded and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products and resulting in presentation to the Washington Medicaid program false records or statements material to false claims, in violation of Wash. Rev. Code § 74.66.020(1)(b).

681. Due to Defendants' conduct, the State of Washington has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Wash. Rev. Code § 74.66.020(1).

682. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

683. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Wash. Rev. Code § 74.66.070. All such expenses, fees, and costs shall be awarded against the defendants.

THIRTY FIFTH CAUSE OF ACTION

VIOLATIONS OF WISCONSIN STATUTES ANNOTATED § 20.931 WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW

684. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

685. As set forth above, Defendants knowingly colluded and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Wisconsin Medicaid program for payment or approval, in violation of Wis. Stat. Ann. § 20.931(2)(a).

686. As set forth above, Defendants knowingly colluded and conspired with each other and various pharmaceutical companies resulting in increased prescribing of said companies' pharmaceutical products resulting in false or fraudulent claims made to be presented or caused to be presented to the Wisconsin Medicaid program for payment or approval, in violation of Wis. Stat. Ann. § 20.931(2)(a).

687. Due to Defendant's conduct, the State of Wisconsin has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Wis. Stat. Ann. § 20.931(2).

688. When successful, the Relator will receive between 15 and 25 percent of the proceeds in cases where the state intervenes; if the state does not intervene the successful Relator will receive between 25 and 30 percent of the proceeds.

689. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Wis. Stat. Ann. § 20.931(11). All such expenses, fees, and costs shall be awarded against the defendants.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment:

1. The Court enter judgment against Medscape, WebMD, CE Outcomes, WebMD Global LLC, WebMD Health Corp., MH SUB I, LLC dba Internet Brands, and Healthcare Performance Consulting, for the maximum amount of fines/penalties, restitution, forfeitures and an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, said damages to be determined through discovery and trial plus a civil penalty of $11,000 for each action in violation of the FCA, and the costs of this action, with interest, including the costs to the United States Government for its expenses related to this action;

2. In the event that the United States Government continues to proceed with this action, Relator be awarded an amount for bringing this action of 25% of the proceeds of the action or the settlement of any such claim;

3. In the event that the United States Government does not proceed with this action, Relator be awarded an amount for collecting the civil penalty and damages of 30% of the proceeds of this action or the settlement of any such claim;

4. The Relator be awarded all costs, attorneys fees, and litigation expenses;

5. The United States Government and Relator receive all relief, both at law and in equity, to which they may reasonably appear entitled.

6. That Relater be awarded the maximum amount allowed pursuant to§ 3730(d) of the False Claims Act.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relater hereby demands a trial by jury.

Dated: October 16, 2023

Respectively submitted,

John M. Restaino, Jr. (California Bar # 138268)
Admitted *Pro Hac Vice*
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GLOSSARY OF KEY ENTITIES AND INDIVIDUALS

Accreditation Council for Continuing Medical Education (ACCME)
Accredits CME (continuing medical education) providers so the providers can offer physicians the CME physicians need to get CME credit to maintain their licenses.

- Graham McMahon, MD, MMSc, current President and Chief Executive Officer, ACCME
- Murray Kopelow, MD, former ACCME President and CEO
- Kate Regnier, Executive Vice President, MA, MBA
- Ed Kennedy, Director, Business Intelligence, Data, and Reporting

Mary Ales, BA
Executive Director, Interstate Postgraduate Medical Association; Co-authored Needs Assessment under direction of Shelly Rodrigues; CO*RE staff

American Pain Society (APS)
Popularized pain as the "fifth vital sign." Helped form, and belonged to, CO*RE. Went bankrupt in 2019 during lawsuits that alleged it was a front for opioid companies.

Charles Argoff, MD
Gave about twenty presentations on opioids at Medscape, including one with the vice president of medical affairs; Independent Content Reviewer for one RPC CO*RE program at Medscape

Doris Auth, PharmD
Associate Director, Drug Safety and Risk Management, FDA; FDA's liaison to MedBiquitous.

Mark Baczkowski
Varied positions at Mylan; on RPC Metrics sub-team; shared more information about the RPC's plans than other experts at MedBiquitous meetings.

Raj Batel
Polaris Solutions; Member of the RPC CE Subteam

Marcus Bender
Polaris Solutions; Member of the RPC CE Subteam

Barrier Analysis
Structured ways to uncover barriers prescribers have to prescribing a particular drug, or class of drugs, such as opioids, and figuring out ways to overcoming them.

David Bazzo, MD
CO*RE Faculty Advisory Panel and Contributing Faculty, Co-author on one CME program, Reviewer and Test Item Writer for two programs.

Sara Benett
Project Manager, Physicians' Institute for Excellence in Medicine; CO*RE staff

Nancy Bennett, PhD
Member, CO*RE Education Advisory Panel; reviewed the HPC report for CO*RE; showed how the data HPC collected (for example, barriers to prescribing opioids) might link to potential educational design.

Julie Bruno, MSW, LCSW
Director, Education and Training, American Academy of Hospice and Palliative Medicine; CO*RE Staff, CO*RE Planner*

Campbell Alliance
Pharmaceutical and management consulting firm acquired by inVentiv Health (now Syneos Health) in 2011. Reminded CE providers of their obligations to the RPC.

Roberto Cardarelli, DO, MPH
Faculty Advisory Panel and Contributing Faculty

Linda Casebeer, PhD
President, CEO of CE Outcomes, Inc. Developed embedded content, often promoting unapproved uses, for Medscape CE beginning in 2004. Co-chair, MedBiquitous Metrics Working Group.

Piyali Chatterjee, aka Piyali Chatterjee-Shin
Senior Director, Medical Education, Medscape; wrote market research reports on CE; co-authored key market research analysis of first thirty RPC-funded CE programs

Michael Cheshire, DO
Clinician and clinical associate professor in West Virginia. Contributor to one program.

clinicaltrials.gov
US database for registered trials; lists six RPC trials whose goal was to test the impact of CE at the population level; no results yet posted even though one trial was expected to be complete in 2016.

Commitment to change
Some CE asks participants what they will do differently as a result of the program, and presents a list of possibilities. Checking off possibilities – a commitment in writing – is associated with making changes.

Confidence
Knowledge influences intention to change practice, especially commitment to change, through its influence on confidence; Medscape almost always measured pre-CE/post-CE as a proxy for change

Continuing Education (CE) Subteam
The group within RPC responsible for all CE-related aspects of the REMS, including educational grant review. In 2015, its ten members were:

- Nathan Kopper and John Decker (Mallinckrodt)
- Bob Kristofco (Pfizer)
- Ekaterina Walker (Purdue Pharma)
- Marsha Stanton (Zogenix/Pfizer)
- Meghana Rao and John West (Campbell Alliance)
- Marcus Bender and Raj Batel (Polaris Solutions)
- Linda Kitlinski (Consultant)

Adle Cohen, MS, PCMN, CCE
Project Manager, Senior Vice President, Physicians' Institute for Excellence in Medicine; CO*RE staff

CO*RE
Originally the RPC funded CE largely from a group of about a dozen professional societies and associates – the CO*RE REMS Partnering Organizations:

- American Academy of Hospice and Palliative Medicine
- American Academy of Physician Assistants
- American Association of Nurse Practitioners
- American College of Emergency Physicians
- American Osteopathic Association
- American Pain Society*
- American Society of Addiction Medicine
- California Academy of Family Physicians
- Healthcare Performance Consulting
- Interstate Postgraduate Medical Association
- Nurse Practitioner Healthcare Foundation
- Medscape
- Physicians' Institute

The Project Lead was Cynthia Kear, MDiv, Senior Vice President, California Academy of Family Physicians. Of the first 6,496 prescribers in the first thirty CE programs, 61% took their CE at Medscape.

Ronald Crossno, MD
Senior National Medical Director, Gentiva Health Services; Faculty Advisory Panel and Contributing Faculty

CS2day
According to a confidential Pfizer/Purdue document, CO*RE's scope, techniques of persuasion, and staff were intended to copy Pfizer's eight-partner CS2day (Cease Smoking Today) collaboration in China. CO*RE originally aimed to educate 650,000 HCPs about opioids, but as of today has reached more than 750,000 physicians, nurse practitioners, and physician assistants who prescribe opioids.

John Decker
Mallinckrodt; Member of the RPC CE Subteam

Arlene Deverman, CAE, CFRE
Vice President, Professional Development, American Society of Addiction Medicine; CO*RE staff

FDA Blueprint
FDA curriculum for extended release/long-acting (ER/LA) opioids, and a later one to covered all opioids. Both created with input from varied stakeholders, including industry

Katherine Galluzzi, DO
Faculty Advisory Panel and Contributing Faculty; co-authored/presented three programs, wrote two test items for two programs.

Harry Gould III
Professor of Neurology and Neuroscience, Louisiana State Health Sciences Center, Independent Content Reviewer for one Medscape CE program

Cynthia (Cyndi) Grimes
Director, CE, Medscape; Participated in MedBiquitous; Co-authored market research of the first thirty RPC-funded Medscape CE programs; Co-authored REMEDIES, a Medscape project for Mallinckrodt.

Carol Havens, MD
Facilitator, Education Advisory Panel; reviewed the HPC report for CO*RE; showed how the data might link to potential educational design. Member, CO*RE Faculty Advisory Panel and Contributing Faculty.

HCP
Healthcare professional

Robin Heyden of HeydenTy
Lead writer, Staff, CO*RE Operations and Management Team; CO*RE Planner*

Neil Heyden
Staff, CO*RE Operations and Management Team; CO*RE Planner*

Healthcare Performance Consulting (HPC)
Under Thomas McKeithan, Jr, MBA, HPC designed material to embed in Medscape CE, sometimes for unapproved uses, and measured the effects with embedded questions, surveys, and interviews.

Amy Holthusen, BA
Learning Strategist, Interstates Postgraduate Medical Association; Co-authored Needs Assessment under direction of Shelly Rodrigues; Independent Contract Reviewer

Randall Hudspeth, PhD, MBA, MS, APRN-CNP
Advanced Practice Pain Management and Palliative Care; Faculty Advisory Panel and Contributing Faculty, Co-author of one program, Test Item Writer for two programs.

InVentiv
Acquired the Campbell Alliance; was acquired by mega consulting biotech company Syneos.

Marcia Jackson, MD
Owner of CME by Design. Member, CO*RE Education Advisory Panel; reviewed the HPC report for CO*RE; showed how HPC data might link to potential educational design. Pfizer grant reviewer.

Pam Jenkins-Wallace, MS, NP
Program Director, Nurse Practitioner Healthcare Foundation; CO*RE Staff

Cynthia Kear, MDiv, CHCP
CO*RE Project lead; Senior Vice President of the California Academy of Family Physicians; Co-authored market research analysis of the first thirty RPC-funded CE programs

Linda Kitlinski
Senior director at Endo; Chair, RPC Metrics Subteam; CE consultant for the RPC; wanted population-level data on results of RPC-funded CE per the FDA; RCP later registered six trials at clinicaltrials.gov for this

Nathan Kopper
Mallinckrodt; Member of the RPC CE Subteam

Carl Kraus, MD
Vice president of medical affairs at Medscape, kicked off Medscape CE program, "Opioid REMS and Safe Use Practices: What Are the Implications Today?" in collaboration with CO*RE; REMS portfolio.

Bob Kristofco
CE Subteam co-chair along with Marsha Stanton; Director of Medical Education at Pfizer Global Medical Grants. Issued multiple RFPs on pain.

Francis Kwakwa, MA
Radiologic Society of North America; Specialist in CE design and evaluation; co-chair, MedBiquitous Metrics Working Group, with Linda Casebeer, PhD, of CE Outcomes, Inc, as co-chair.

Chris Larrison, BA
Partner at Healthcare Performance Consulting; worked with Thomas McKeithen, Jr, MBA

Marie-Michele Leger, MPH PA-C
CO*RE Planner*

Herbert Malinoff, MD
Adjunct Clinical Instructor, Department of Anesthesiology, University of Michigan Health System, Ann Arbor; CO*RE Planner*

Sharon McGill, MPH
Director, Department of Quality and Research, American Osteopathic Association, CO*RE staff

Michele McKay
CO*RE staff

MedBiquitous
Founded by the RPC, now owned by the Association of American Medical Colleges, MedBiquitous consolidates, evaluates, and transfers information on HCPs. Syneos is a member, "on half of the RPC."

Medical Education Metrics (MEMS)
A consistent format and data structure to represent healthcare professional knowledge, especially from CE, so information can be exchanged online between disparate systems and organizations.

Penny Mills, MBA
Executive Vice President and CEO, American Society of Addiction Medicine, CO*RE Executive Team

Donald E. Moore, Jr, PhD
Developed Moore's model of learning. Member, CO*RE Education Advisory Panel; reviewed the HPC report for CO*RE; showed how the data HPC collected might link to potential educational design.

Moore's Model of Learning
Evidence-based heuristic showing levels of learning in CE. Depicted as a pyramid in Medscape Sales deck and elsewhere, it depicts level 4 as, "performance." The purpose of buying CE is to get Level 4 change.

Opioids
Two kinds: extended release/long-acting (ER/LA) and immediate release (IR). Opioids have specific approved uses, such as for cancer pain, but are not intended for, and are not ideal for, chronic pain

Kate Nisbet, BBA, MDA
Director of Health Systems Education, Interstate Postgraduate Medical Association; CO*RE Staff

Anne Norman, DNP, APRN, FNP-BC
Associate Vice President of Education, American Association of Nurse Practitioners; CO*RE Executive Committee; CO*RE Planner*

Participants
HCPs who complete a CE program (vs non-completers, or readers). This dichotomy is one of several that allow researchers to estimate the influence a CE program has had.

Program and Activity Reporting System (PARS)
ACCME's database for collecting, and sharing, CE information between organization. The system uses MEMS (Medical Education Metrics).

Eric D. Peterson, EdD, FACEHP
Senior Director, Performance Improvement CME, American Academy of Physician Assistants; CO*RE Planner*

Polaris Solutions
Aggregates data on RPC-funded CE on opioids. CE providers must agree to allow the ACCME to share their data with a third-party aggregator as a condition of RPC funding.

Program of Prominence
Large scale, enduring, "browse and learn" destination consisting of an online page with links to CE programs and other material. Usually promotes a single product. See the Medscape Sales Deck.

Meghana Rao
Primary Point of Contact for the Campbell Alliance; Member of the RPC CE Subteam

REMS Program Companies (RPC)
Pfizer and Purdue began a consortium of opioid companies, the RPC, to fund CE for prescribers that would theoretically follow the FDA's Blueprint for this education.

Risk Evaluation and Mitigation Strategies (REMS)
FDA-created protocols for users of potentially dangerous drugs to minimize risk. For opioids, the FDA mandated that prescribers take CE funded by opioid manufacturers – the first time a REMS included CE.

Jennifer Reinard
Education Manager, American Pain Society, was on the CO*RE staff along with the APS CEO, Catherine Underwood. APS popularized pain as the, "fifth vital sign" and otherwise promoted opioid use

Dennis Rivenburgh, MS, ATC, PA-C, DFAAPA
Senior Physician Assistant at Johns Hopkins; (Added to Faculty Advisory Panel when Seddon Savage, MD, MS, was deleted) Faculty Advisory Panel and Contributing Faculty, Test Item Writer for Two Programs

Sheila Robertson
Member, CO*RE Operations and Project Management teams; Lead writer

Shelly Rodrigues, CAE, FACEHP
Deputy Executive Vice President, California Academy of Family Physician; Lead on writing team for Needs Assessment with Amy Holthusen and Mary Ales; CO*RE staff and Planner* with Cynthia Kear

Edwin A. Salsitz, MD
Beth Israel Medical Center, Division of Chemical Dependency, Assistant Professor, Albert Einstein College of Medicine; Faculty Advisory Panel and Contributing Faculty

Seddon Savage, MD, MS
Planning Committee (was replaced by Dennis Rivenburgh, MS, ATC, PA-c, DFAAPA)

Cynthia Singh
Director Grants and Foundation Development, American College of Emergency Physicians; CO*RE staff

Valerie Smothers, MA
Deputy Director, MedBiquitous; has an tech background; led RPC project with Metrics Working Group (Francis Kwakwa and Linda Casebeer, co-chairs) and Activity Report Working Group (James Fiore, chair)

Barbara St. Marie, PhD, ANP-BC
Supervisor, Pain and Palliative Care, Adult Gerontology Nurse Practitioner, Pain Management, University of Minnesota Medical Center, Fairview; Faculty Advisory Panel and Contributing Faculty

Marsha Stanton, PhD, RN
Focused on education at several pharmaceutical companies, including Purdue and Pfizer. Part of CS2Day; helped organize RPC. CE Subteam co-chair along with Bob Kristofco of Pfizer.

Stephanie Townsell, MPH
Public Health Project Manager, American Osteopathic Association; CO*RE staff

Syneos
Global biopharmaceutical consultant company, now a member of MedBiquitous, ”on behalf of the RPC.“ The Campbell Alliance is part of inVentiv, which is part of Syneos. All three entities have helped the RPC.

Catherine Underwood
American Pain Society CEO; represented APS in CO*RE and was CO*RE staff; helped Cynthia Kear create the agenda for a summit meeting

Lori Vega
Director, Strategic Partnerships, American College of Emergency; CO*RE staff

Ekaterina Walker
Purdue Pharma; Member of the RPC CE Subteam

Leah Wang
Vice President or Senior Vice President, Site Operations, Medscape; piloted IT at MedBiquitous, such as seamlessly sending data to Medscape's large membership at the American Osteopathic Association

John West
Primary Point of Contact for the Campbell Alliance; Member of the RPC CE Subteam

Phyllis Zimmer, MN, FNP, FAAN
President, Nurse Practitioner Healthcare Foundation

*APS closed amidst the Senate Finance Committee investigation into its financial ties to pharmaceutical companies.
**Planner = CO*RE Content developer, planner, reviewer